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Licensing manual for ozone depleting substances (ODS)

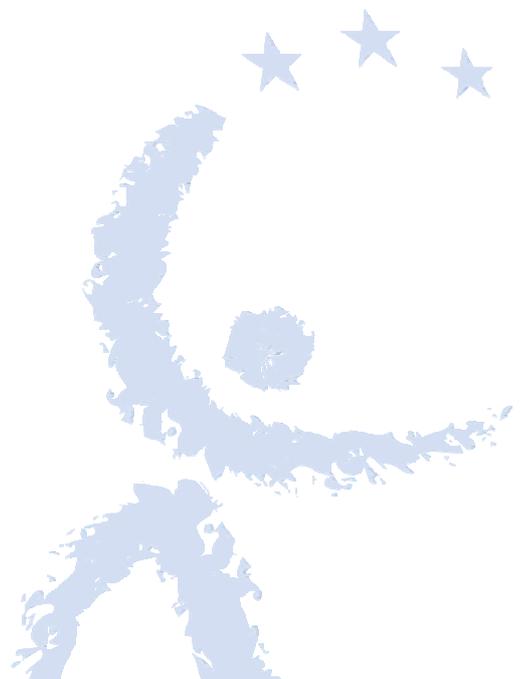
PART X

LABORATORIES AND SUPPLIERS OF ODS FOR LABORATORY AND ANALYTICAL USES

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ABBREVIATIONS

BCM	Bromochloromethane
CFC	Chlorofluorocarbons
CTC	Carbon tetrachloride (Tetrachloromethane)
EU	European Union
HAL	Halon
HBFC	Hydrobromofluorocarbons
HCFC	Hydrochlorofluorocarbons
L&A	Laboratory and analytical uses
MB	Methyl bromide (Bromomethane)
ODS	Ozone depleting substance (in this document only substances listed in Annex I to the Regulation)
TCA	1,1,1-Trichloroethane
UNEP	United Nations Environment Programme

Important note:

The information given in this document is of a general nature and for information purposes only and should not be understood as legally binding or as legal guidance. It is not necessarily comprehensive, complete or up to date. It may be subject to change without notice, in particular following revisions of the Montreal Protocol or other relevant legal acts. The user is responsible for ensuring compliance with existing legislation. The European Commission accepts no responsibility or liability whatsoever with regard to the information contained in this document.

1. GENERAL INFORMATION

1.1. The importance of a healthy ozone layer

The ozone layer in the upper atmosphere protects humans and other organisms from solar UV radiation. In the 1970s scientists discovered that certain man-made chemicals deplete the ozone layer, leading to an increased level of UV radiation.

Overexposure to UV radiation gives rise to a number of serious health risks for humans. It causes not only sunburn but also greater incidences of skin cancer and eye cataracts. Children and light skinned people are particularly vulnerable. There are also serious impacts for biodiversity. For example, increased UV radiation reduces the levels of plankton in the oceans and subsequently diminishes fish stocks. It can also have adverse effects on plant growth, thus reducing agricultural productivity. A direct negative economic impact is the reduced lifespan of certain materials such as plastics.

Most man-made ozone depleting substances (ODS) are also very potent greenhouse gases. Some of them are up to 14000 times stronger than CO₂. Eliminating such substances thus also contributes to the prevention of climate change. The phase-out of ozone depleting substances has so far delayed the impact of climate change by 8-12 years.

It is therefore important to minimise the use of ODS as much as possible to protect the ozone layer, the climate and our health.

1.2. The legal situation

Regulation (EC) No 1005/2009¹ (the Regulation) prohibits the use of ozone depleting substances that are listed in Annex I to the Regulation. Hereinafter, these substances are referred to as »ozone depleting substances« or »ODS«. ² Substances listed in Annex II to the Regulation are not affected. Laboratory and analytical uses are exempted from this ban under certain conditions. These conditions are explained in this document.

Regulation (EU) No 291/2011³ lays down a non-exhaustive list of laboratory and analytical uses that are considered as essential, and a second list of uses that are considered as non-essential.

Undertakings that wish to take advantage of the exemption for essential laboratory or analytical uses need to register in the Laboratory-ODS-database to obtain an Identification Number (ID Number).

¹ Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer, OJ L 286, 31.10.2009, p. 1 (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009R1005:EN:NOT>).

² An annotated non-exhaustive list of ODS is available from the CIRCA online forum on licensing and reporting (http://circa.europa.eu/Public/irc/env/review_2037/library).

³ Commission Regulation (EU) No 291/2011 of 24 March 2011 on essential uses of controlled substances other than hydrochlorofluorocarbons for laboratory and analytical purposes in the Union under Regulation (EC) No 1005/2009 of the European Parliament and of the Council on substances that deplete the ozone layer, OJ L 79, 25.3.2011, p. 4 (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011R0291:EN:NOT>).

This manual applies to those undertakings that wish to use ODS for laboratory or analytical uses and purchase their supplies from an undertaking based in the European Union. It also applies to distributors of ODS for laboratory or analytical uses that buy ODS from or sell ODS to undertakings located in the European Community.

Undertakings obtaining their supplies from a company outside the European Union should refer to Part VI of this manual dealing with imports. Undertakings that produce ODS for laboratory or analytical uses themselves or have them produced for them by another undertaking should refer to Part VIII of this manual dealing with production.

1.3. Substances concerned

The substances concerned are listed in Annex I to the Regulation.¹ They are split into nine groups, as shown in the table below.

Group	Abbreviation	Description
Groups I and II	CFC	Chlorofluorocarbons including: 1,1,2-Trichloro-1,2,2-trifluoroethane (CFC-113)
Group III	HAL	Halons (1211, 1301 and 2402)
Group IV	CTC	Carbon tetrachloride (Tetrachloromethane)
Group V	TCA	1,1,1-Trichloroethane
Group VI	MB	Methyl bromide (Bromomethane)
Group VII	HBFC	Hydrobromofluorocarbons
Group VIII	HCFC	Hydrochlorofluorocarbons
Group IX	BCM	Bromochloromethane

Important:

- ! All isomers and all forms of the above-mentioned substances are governed by the Regulation, including, for example, radioactively marked substances.

Any mixture, product or equipment that contains these substances or relies on them in order to function is also covered by the Regulation.

Substances listed in Annex II to the Regulation (new substances) are not subject to the rules outlined in this document.

Any quantity of these substances is concerned. There is no threshold allowing exemptions.

1.4. Quality requirements for laboratory chemicals

In addition to the use restrictions, ODS used for essential laboratory or analytical uses need to match certain specifications as described in Annex V to the Regulation.

Substance	Minimum purity requirement
1,1,1-trichloroethane	99.0 %
Carbon tetrachloride	99.5 %
CFC-11, CFC-12, CFC-13, CFC-113, CFC-114	99.5 %
Other ODS with boiling point >20 °C	99.5 %
Other ODS with boiling point <20 °C	99.0 %

These high purity substances and mixtures containing controlled substances may be placed on the market only:

- in re-closable containers or high pressure cylinders smaller than three litres, or
- in 10 millilitre or smaller glass ampoules, and
- where marked clearly as substances that deplete the ozone layer, restricted to laboratory use and analytical purposes, and
- specifying that used or surplus substances should be collected and recycled, if practical. The material should be destroyed if recycling is not practical.

1.5. Definitions

1.5.1. Analytical use

An analytical use is any use of ODS for the identification of compounds or the determination of the proportions of components in a mixture, for example the use of ODS as reference material.

1.5.2. Laboratory use

Any use of ODS in a laboratory that is not an analytical use, for example laboratory feedstock uses or uses of ODS in a toxicological study.

1.5.3. Laboratory feedstock use

Laboratory feedstock use is the use of an ODS in a laboratory in a chemical synthesis process where the ODS is a reagent in the chemical transformation and is chemically converted from its original composition. This is different from cases where the ODS is used for example as a solvent or catalyst.

A use qualifies as laboratory feedstock use only if the product of the reaction is used in laboratories within your own company for research and development. The product or potential products from subsequent synthesis may not be given to third persons (whether or not against payment).

If the end-product is for example sold or given to clients for testing, this is no longer considered as laboratory feedstock use but as normal feedstock use as defined in Regulation (EC) No 1005/2009 and subject to the relevant provisions.

1.5.4. Laboratory ODS production

Laboratory ODS production is the production (synthesis) of an ODS in a laboratory for the purpose of research and development as an intermediate or end product. Such production will only qualify as laboratory ODS production if:

- the ODS is used in laboratories within your own undertaking for research and development and the ODS is not made available to third persons (whether or not against payment), and
- the ODS is not used for subsequent production of a product that is eventually placed on the market (whether or not against payment).

In any other case the production will be considered as production as defined in Regulation (EC) No 1005/2009 and will be subject to the relevant provisions.

2. PERMITTED AND PROHIBITED USES

2.1. The concept of essential use

The use of ODS for laboratory or analytical uses is only allowed if the use is essential. A use is considered essential only in those cases where there is no technically and economically feasible alternative or where the alternative is less acceptable from the standpoint of the environment and health.

There is no comprehensive list of allowed ODS uses for laboratories. A non-exhaustive list of essential and non-essential uses is provided below. It is based on the list in Regulation (EU) No 291/2011. Whether or not the use is essential has to be evaluated in the general risk analysis that has to be carried out before dangerous substances are used (e.g. under Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work).

All ODS are classified as dangerous substances under the chemicals legislation. Not only are they dangerous for the environment but some are also a danger to human health. Since less dangerous alternatives are readily available for most uses, normally there is no need to use ODS.

2.2. Occupational health and safety aspects

The most popular ODS in laboratories are 1,1,1-trichloroethane, 1,2,2-Trichlorotrifluoroethane (CFC-113), carbon tetrachloride and methyl bromide. These substances are not only dangerous for the ozone layer but also give rise to other hazards. 1,1,1-trichloroethane is harmful. Carbon tetrachloride and methyl bromide are carcinogenic and mutagenic. Therefore, their use is also severely restricted under the provisions on occupational health and safety.

Important:

- ! The combination of health and environmental hazards of these ODS makes a favourable outcome in a risk analysis very unlikely. This further limits the legal possibilities to use these substances.

2.3. Non-essential uses (prohibited uses)

The following uses can never be considered as essential laboratory or analytical uses. Therefore, using ODS for the following applications is always prohibited:

- a) refrigeration and air-conditioning equipment used in laboratories, including refrigerated laboratory equipment such as ultra-centrifuges;
- b) cleaning, reworking, repair, or rebuilding of electronic components or assemblies;
- c) preservation of publications and archives;
- d) sterilisation of materials in a laboratory;
- e) any use in primary or secondary education;
- f) as components in experimental chemistry kits available to the general public and not intended for use in higher education;
- g) for cleaning or drying purposes, including the removal of grease from glassware and other equipment;
- h) for the determination of hydrocarbons, oils and greases in water, soil, air or waste;
- i) testing of tar in road paving materials;
- j) forensic finger-printing;
- k) testing of organic matter in coal;
- l) as a solvent in the determination of cyanocobalamin (Vitamin B12) and the bromine index;
- m) in methods that use the selective solubility in the controlled substance, including the determination of cascarosides, thyroid extracts, and the formation of picrates;⁴
- n) to preconcentrate analytes in chromatographic methods (e.g. high performance liquid chromatography (HPLC), gas chromatography (GC) adsorption chromatography), atomic absorption spectroscopy (AAS), inductively coupled plasma spectroscopy (ICP), X-ray fluorescence analysis;⁵
- o) for the determination of the iodine index in fats and oils;⁶

⁴ This includes all sorts of extraction processes such as Soxhlet extractions, liquid-liquid extraction, solid-phase extractions and recrystallisations. It also covers all kinds of Thin Layer Chromatography (TLC).

⁵ Pre-concentration includes for example processes such as liquid-liquid or solid-phase extraction. This also covers the use of ODS as solvents in thin layer chromatography or their use as an eluent in HPLC.

⁶ Although this is limited to fats and oils any other matrix for which alternative solvents are available constitutes a non-essential use covered by the general prohibition in (p).

- p) any other laboratory or analytical use for which a technically and economically feasible alternative is available.

Note that although not listed explicitly above, most cases in which ODS are used as solvents, diluents or eluents are not essential because alternative solvents can be used.

2.4. Essential uses (permitted uses)

The following uses can usually be considered as essential laboratory or analytical uses. Their use is permitted provided that no non-ODS alternative is available.

- a) the use of controlled substances as a reference or standard:
- to calibrate equipment which uses controlled substances,
 - to monitor emission levels of controlled substances,
 - to determine residue levels of controlled substances in goods, plants and commodities;
- b) the use of controlled substances in laboratory toxicological studies;
- c) laboratory uses in which the controlled substance is transformed in a chemical reaction (laboratory feedstock uses);
- d) the use of methyl bromide inside a laboratory to compare the efficacy of methyl bromide and its alternatives;
- e) the use of carbon tetrachloride as a solvent for bromination reactions involving N-bromosuccinimide (NBS);
- f) the use of carbon tetrachloride as a chain transfer agent in free-radical polymerisation reactions;
- g) any other laboratory or analytical use for which a technically and economically feasible alternative is not available.

2.5. Other uses for which alternatives are usually available

In its 2009 progress report the Technology and Economic Assessment Panel established under the Montreal Protocol identified a number of procedures for which alternatives to the use of ODS should usually be available. Hence ODS should be avoided for the following uses:

- a) Analyses in which the ODS is used as a solvent for spectroscopic measurement, including the recording of infrared and nuclear magnetic resonance spectra;
- b) Analyses in which the ODS is used as a solvent for electrochemical methods;
- c) Titration of iodine with thiosulfate (iodometric analyses), including the determination of iodine, copper, arsenic or sulphur;
- d) Miscellaneous analyses, including
- (1) stiffness of leather,
 - (2) jellification point,

- (3) specific weight of cement,
 - (4) gas mask cartridge breakthrough;
- e) Use as a solvent in organic chemical synthesis reactions, including O- and N-difluoromethylation.

2.6. ODS in standard methods and standards (such as ISO, EN, ASTM)

The fact that an ODS is prescribed in a standard does not make the use essential. If the use is considered non-essential above, it remains prohibited even if it is prescribed by a standard. Note that standards have no legal force. They cannot overrule a regulation.

Most standards that previously prescribed ODS (e.g. for the determination of hydrocarbons in water) have meanwhile been replaced by methods that no longer use ODS (see also Annex II to this document). Hence the use of ODS can no longer be considered as state-of-the-art.

2.7. Alternatives

Information on alternative methods not depending on ODS is widely available on the internet and in the technical press. The following are some of the documents that provide information on potentially suitable alternatives:

- Use of ozone depleting substances in laboratories (Nordic Council project)
<http://www.norden.org/en/publications/publications/2003-516>
- 2009 Progress Report of the Technology and Economic Assessment Panel (pages 51-56)
http://ozone.unep.org/Assessment_Panels/TEAP/Reports/TEAP_Reports/Teap_progress_report_May2009.pdf
- 2008 Progress Report of the Technology and Economic Assessment Panel (pages 54-62)
http://ozone.unep.org/Assessment_Panels/TEAP/Reports/TEAP_Reports/Teap_progress_report_May2008.pdf

A non-exhaustive list of alternative methods is also available in Annex II to this document.

3. THE ID NUMBER

3.1. General issues

Article 10(4) of the Regulation stipulates that any undertaking using ODS for laboratory or analytical uses must register in the Laboratory-ODS-database (see next chapter). As a result of that registration an Identification Number (ID Number) is issued. The ID Number proves that the holder is registered and authorised to purchase or trade ODS for essential laboratory and analytical uses.

Important:

- ! The ID Number does not confirm that the use is essential and thus permitted.

This requirement applies to any end user of ODS for essential laboratory or analytical uses such as laboratories of private companies, laboratories of public institutions, research centres or universities.

It also applies to distributors of ODS based in the European Union making available (e.g. by selling) ODS that were not produced or imported by themselves to other undertakings based in the European Union. To avoid any illegal placing on the market, ODS for essential laboratory or analytical uses should only be sold to customers within the EU market if the customer is able to provide an ID Number. Distributors may be requested by their national competent authorities to demonstrate that sales took place only to customers holding an ID Number. While formally not required, it has become common practice to request an end-user statement since this is already required for other kinds of controlled chemicals.

3.2. Validity of the ID Number

Currently the validity of an ID Number is not time-limited and it does not need to be renewed. It can be used for multiple purchases over several years. However, you must keep the information provided in the declaration form up to date. If changes occur, the ID Number declaration must be updated.

It is not necessary for each department or user within an undertaking to apply for an individual ID Number. An ID Number will always be valid for a whole legal entity regardless of the number of actual users or the quantity of ODS used.

The Commission acknowledges that it is sometimes more practical to have more than one ID Number within a legal entity in certain cases, e.g. for each site of larger entities. However, change of personnel is not an acceptable reason to apply for more than one ID number.

3.3. Verifying the validity of an ID Number

Under the Regulation a distributor of ODS is not required to verify the validity of an ID Number. However, to be prepared for potential inspections it is usually advisable to request and file the ID Numbers of customers, as with end-user statements under other legislation. In case of doubt about the validity of an ID number please contact the European Commission.

4. THE LABORATORY-ODS-DATABASE

To receive an ID Number, register online in the Laboratory-ODS-database at http://ec.europa.eu/clima/policies/ozone/ods_en.htm (see picture X/1).

On the same website you will find the privacy statement for the ODS-database pursuant to Regulation (EC) No 45/2001 on the protection of personal data.



Picture X/1: Login page

4.1. The registration procedure

Click on the corresponding link to open the registration form in a new window (see picture X/2).

4.1.1. General information

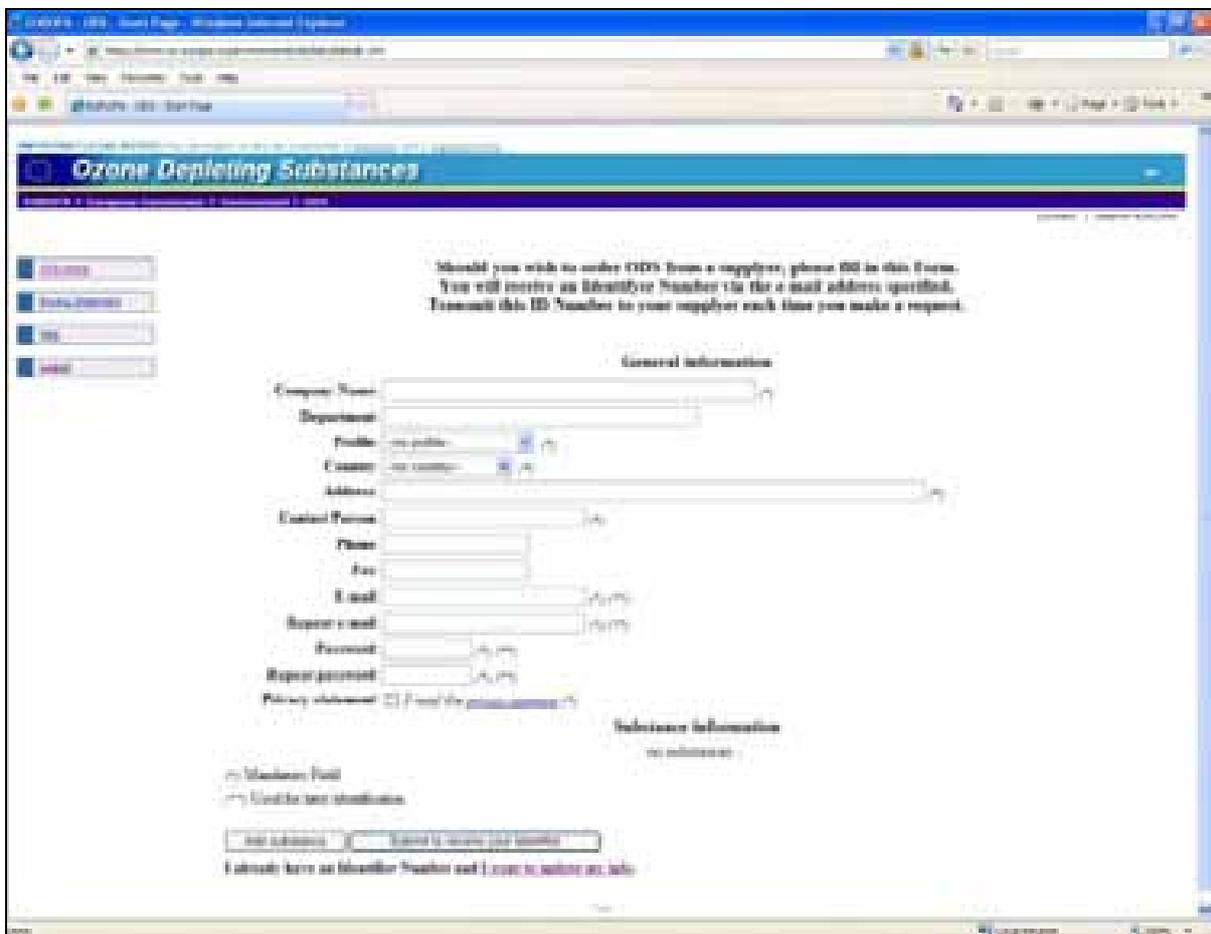
In the upper part of the registration form enter your general contact information. The following table provides details on how to complete the individual fields.

Field	Required information
'Company name'	Enter the full name of the undertaking (including its legal form) in this field. Do not use the name of a department or a particular laboratory unit within an undertaking.
'Department'	Provide the name of the department, unit or laboratory within the undertaking for which the ID Number is to be valid. If the ID Number is to be valid for the whole undertaking do not provide any information in this field.

Field	Required information
'Profile'	<p>From the listed options, the user's type of business needs to be selected from the drop-down menu:</p> <ul style="list-style-type: none"> • 'Private laboratory' (this includes laboratories of all types of private companies) • 'Government laboratory' (this includes all sorts of laboratories of public institutions unless another category applies) • 'University' (this includes all kinds of post-secondary education institutions, such as vocational schools) • 'School'⁷ (this covers only primary and secondary education) • 'Other' • 'Distributors' • 'Research institute' (this refers to public research facilities. Research facilities of private entities fall under 'private laboratory')
'Country'	Select the Member State in which your undertaking is located from the drop-down menu.
'Address'	Give the full address of your undertaking. This must include the street and number, the post code and the city. A post office box address is not allowed here.
'Contact person'	Full name (first name and family name) of the contact person or name of the department responsible
'Phone'	Telephone number of the contact person or the department responsible
'Fax'	Fax number of the contact person or the department responsible
'E-mail'	E-mail address of the contact person or the department responsible. You must enter the e-mail address twice to ensure that you have not made any typing error. This e-mail address is later used as the user name for login.
'Password'	<p>Passwords will expire automatically 180 days after being changed or (re-)initialised. When logging in a warning is given five days before the password expires. If you attempt to log in more than five days later you will be requested to enter a new password.</p> <ul style="list-style-type: none"> • A password must contain at least 10 characters from three out of four different groups: <ul style="list-style-type: none"> (1) Upper case: A to Z; (2) Lower case: a to z; (3) Numeric: 0 to 9;

⁷ The use of ODS in school laboratories is usually considered non-essential and thus prohibited.

Field	Required information
	<p>(4) Special characters: !"#\$%&'()*+,-./:;<=>?@[\\^_`{ }~.</p> <ul style="list-style-type: none"> The password cannot be identical to your user name. You cannot use a password that has been used before. A password cannot be changed again until it is at least one day old. <p>The password needs to be keyed in twice to ensure that you have not made any typing error.</p>
'Privacy statement'	Read the privacy statement and tick the checkbox to confirm that you have read it.



Picture X/2: Registration form

Substance information

Substance: Carbon tetrachloride [55-23-5]

Use: Analytical use - Carrier - Analytical equipment (spectroscopy, chromatography)

Provide here a short description of the use, for example: "Determination of CFC by gas chromatography according to method ISO 12345"

Use detail:

Estimated annual demand: < 0.1 kg

List the name and address of your potential suppliers

Supplier:

(*) Mandatory Field
(**) Used for later identification

I already have an Identifier Number and [I want to update my info.](#)

Picture X/3: Declaration form

4.1.2. Declaration

After completing the general information, click on ‘Add substance’ to open the substance information form (see picture X/3). Provide information here on the substances, uses and estimated demand. All fields of the declaration form must be completed; submitting an incomplete form will generate an error message.

Field	Required information
'Substance'	Select the name of the substance from the drop-down menu.
'Use'	Select the applicable use category from the drop-down menu. Examples of uses for the different categories are available in Annex I to this document.
'Use detail'	<p>In this field provide a brief description of the use.</p> <p>If the use is described in a nationally or internationally accepted standard (e.g. EN, ISO, ASTM) a reference to that standard is sufficient (for example: »Determination of substance x by method ISO 12345«).</p> <p>If the use is not according to such a standard, it should be described in more detail (e.g. »Analysis of substance x by gas chromatography«, or »Use of CFC-12 as feedstock for the synthesis of substance z«). This description must make it clear what the role of the ODS in the use is.</p> <p>Examples:</p>

Field	Required information
	<ul style="list-style-type: none"> • Don't write: Determination of residues Write: Use of carbon tetrachloride as reference material for the determination of residues in waste water by gas chromatography according to ISO 1234. • Don't write: Synthesis of PTFE Write: Use of chlorodifluoromethane as feedstock for the synthesis of polytetrafluorethylene. • Don't write: Reaction solvent Write: Use of carbon tetrachloride as a solvent in the bromination of chemical xyz with NBS. <p>A maximum of 255 characters is allowed in this field.</p>
'Estimated annual demand'	Select the range of the estimated annual demand from the drop-down menu.
'Supplier'	<p>Provide the name and address (street and number, city, country) of the supplier of the substance. If necessary more than one supplier can be provided in this field.</p> <p>The maximum number of characters allowed in this field is 255.</p>

If more than one ODS is used, or if one ODS is used for various uses, the above information needs to be provided for each substance/use combination. This can be done by completing the declaration form several times. Each time you click on the button 'Add to the declaration' the information is saved in the declaration and a new declaration line is added to the declaration.

Click on 'Delete Substance' below the corresponding declaration line to delete this line in the declaration.

4.1.3. Submission

Once the registration and declaration form has been completed click on 'Submit to receive your identifier' to send the declaration to the European Commission. Once this has been done the declaration part is blocked and can no longer be edited (see below for how to provide updates).

A few minutes after the submission, you will receive an automatically generated e-mail with the requested ID Number.

Note that an ID Number can be revoked by the Commission if later checks reveal that the form has not been completed properly or if the use is not essential (see above). In these cases the competent authority in the Member State concerned will be informed accordingly for follow-up. Beware that the use of ODS for non-essential use is illegal and subject to fines (see chapter on penalties below).

If the e-mail with the ID Number does not arrive within 24 hours contact the European Commission for verification. Do not try to register again. Check your spam folder to ensure that the e-mail was not filtered by mistake.

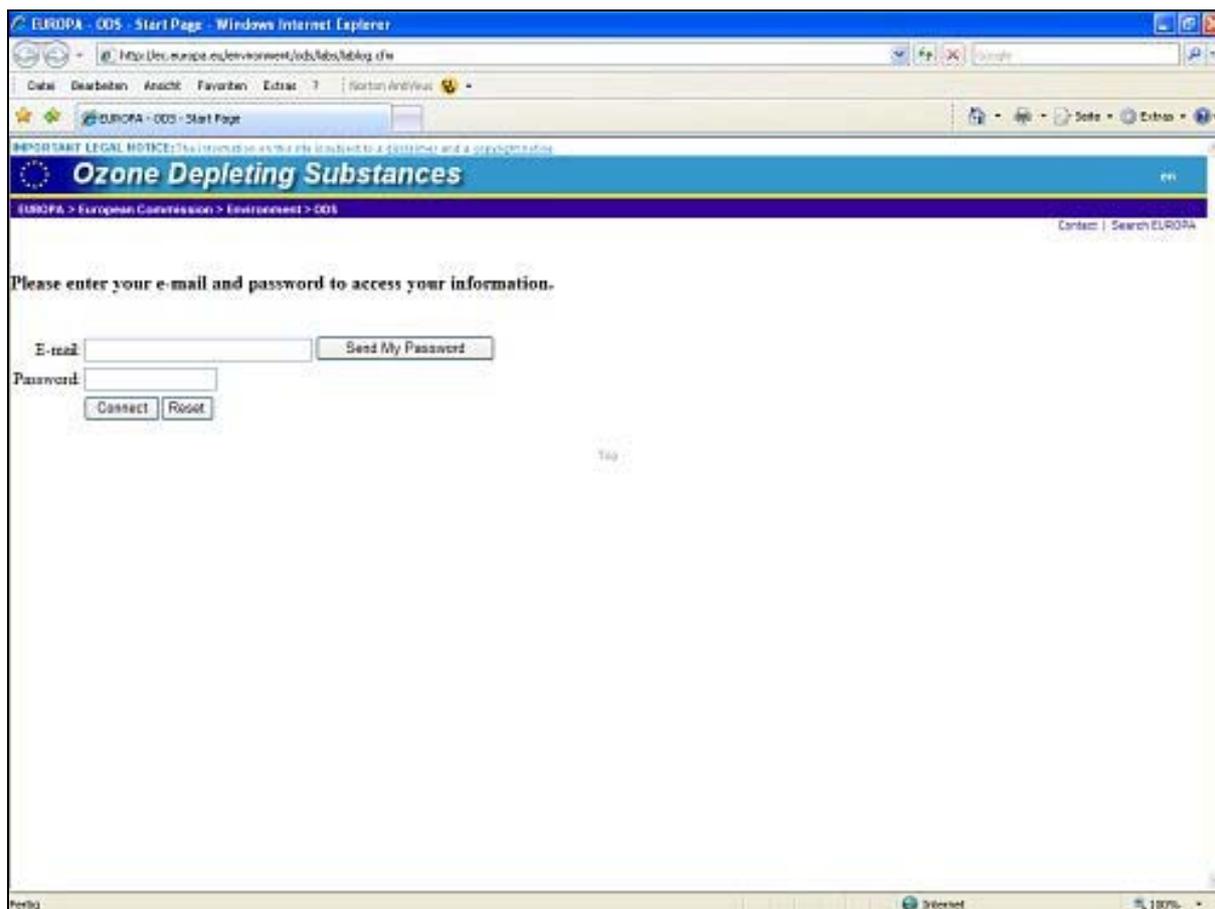
4.2. Options for already registered users

Registered users of the Laboratory-ODS-database always have the option to:

- update the saved contact information for the undertaking,
- update the use declaration,
- change the password,
- check the ID Number again,
- ask for the password to be sent again.

4.2.1. Login

On the page http://ec.europa.eu/clima/policies/ozone/ods_en.htm you can log in to the ODS-database with your e-mail address and password. To log in click on the login picture or on the login link in the Laboratory-ODS-database. In the form that appears (see picture X/4) enter the e-mail address and password. Click on 'connect' to start login.

The image shows a screenshot of a web browser window titled "EUROPA - ODS - Start Page - Windows Internet Explorer". The address bar shows the URL "http://ec.europa.eu/environment/ods/labs/lablog.htm". The browser's menu bar includes "Datei", "Bearbeiten", "Ansicht", "Favoriten", "Extras", and "?". The browser's toolbar shows "EUROPA - ODS - Start Page" and navigation icons. The main content area features a blue banner with the text "Ozone Depleting Substances" and a "Contact" link. Below the banner, there is a navigation path: "EUROPA > European Commission > Environment > ODS". The main heading reads "Please enter your e-mail and password to access your information." Below this heading, there are two input fields: "E-mail:" and "Password:". To the right of the "E-mail:" field is a button labeled "Send My Password". Below the "Password:" field are two buttons: "Connect" and "Reset". The browser's status bar at the bottom shows "Perth", "Internet", and "100%".

Picture X/4: Login form

4.2.2. Forgotten password

If you have forgotten your password you can retrieve it again by clicking on the corresponding link on the page http://ec.europa.eu/clima/policies/ozone/ods_en.htm. This will again open the login form. Enter the e-mail address and click on 'Send my password'. If the e-mail address corresponds to a registered user, an automatic e-mail with the password will be sent to the e-mail address.

The screenshot shows a web browser window displaying the 'Ozone Depleting Substances' database interface. The page title is 'Ozone Depleting Substances'. On the left, there are navigation buttons for 'Home', 'Introduction', 'ODS', and 'FAQ'. The main content area is titled 'General information' and contains a form with the following fields: 'Address' (with a tooltip 'Using our ODS labels you register'), 'Custom Prefix' (with a tooltip ''), 'Phone' (+31 20 491 4200), 'Fax' (+31 20 491 4200), 'Email' (with a tooltip ''), 'Password' (with a tooltip ''), and 'Expires' (2011-2012). Below this is a section for 'Substance information' with a tooltip 'The declaration must be submitted to the authorities. Please contact the authorities for this matter'. It includes 'Reference ODS 111', 'Use Declaration - Reference - General', and 'Use Declaration - Reference - General'. At the bottom, there is a 'Submit to update data' button.

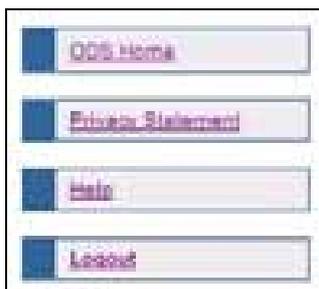
Picture X/5: Laboratory-ODS-database

4.2.3. User data

After logging into the Laboratory-ODS-database (see picture X/5) you will have the option to update the relevant general information. The ID Number is displayed as well. If data have been changed, click on 'Submit to update data' to save the changes.

The data relating to declared substances cannot be changed. If an update is necessary contact the Commission to have the declaration form re-opened.

4.2.4. Navigation pane



Picture X/6: Navigation pane

The navigation pane (see picture X/6) is displayed on the left-hand side of the screen.

Click on the buttons 'ODS Home' or 'Logout' to log off from the Laboratory-ODS-database and return to the ODS homepage on the internet.

'Privacy Statement' opens the privacy statement for the ODS-database.

'Help' will open the CIRCA online forum for licensing and reporting of ODS where you will find all supporting documentation.

4.2.5. Updating the declaration after submission

If the declaration needs to be updated (e.g. when a substance or a use needs to be added) contact the European Commission to have the declaration re-opened. The registration and declaration form will then be made available again in editing mode. You will have five days to update the declaration before it is closed again.

5. PENALTIES

Under Directive 2008/99/EC on the protection of the environment by criminal law, the illegal production, importation, exportation, placing on the market or use of ODS is to be considered an offence when committed intentionally or with at least serious negligence. Penalties are in place under national law in the Member States.

Therefore:

- As an end user: make sure that the use is really essential.
- As a distributor: make sure that your client is using the goods for an essential laboratory or analytical use. Placing on the market for non-essential uses would be illegal.

6. OTHER ISSUES

6.1. Contact information

A list of contact points in the competent authorities in the Member States is available from the CIRCA online forum at http://circa.europa.eu/Public/irc/env/review_2037/library.

Do feel free to contact the European Commission by e-mail at: clima-ods@ec.europa.eu. Additional contact information is available from the CIRCA online forum.

6.2. Record of changes to the document

Version	Changes
1 (2003)	New document.
2 (2006)	Updating, enhanced formatting and inclusion of contact data. Additional language versions for EU-10 Member States.
3 (2007)	Updating of internet links and contact data. Additional language versions for Bulgarian and Romanian.
4 (5/2008)	Major extension of the previous information document, now describing the functions of the Laboratory ODS database and the applicable legislation.
5 (11/2009)	Complete overhaul of the document to reflect the transition from Regulation (EC) No 2037/2000 to Regulation (EC) No 1005/2009.
6 (06/2011)	Complete overhaul of the document. Additional information on essential and non-essential uses following the entry into force of Regulation (EU) No 291/2011. Addition of information on alternatives.

7. ANNEXES

7.1. Annex I: Use categories and examples

Category	Explanation
‘Analytical use — Carrier — Analytical equipment (spectroscopy, chromatography)’	Use of ODS as a carrier (e.g. as a carrier gas in ETV or an eluent in HPLC) in instrumental analysis. Nowadays these uses have usually become non-essential.
‘Analytical use — Carrier — Titration’	Use of ODS as a solvent or diluent in a titration. Nowadays these uses have usually become non-essential.
‘Analytical use — Diluent — Measuring drug purity and residual determination’	Use of ODS as a solvent or diluent in the measurement of purities or impurities (usually with instrumental methods). Nowadays these uses have usually become non-essential.
‘Analytical use — Diluent — Microchemical methods to determine molecular weight or oxygen’	Use of ODS in the determination of molecular weight or oxygen. Nowadays these uses have usually become non-essential.
‘Analytical use — Diluent — Zinc, copper, cadmium detection in plants and food’	Use of ODS as a solvent or diluent in the determination of zinc, copper or cadmium. Nowadays these uses have usually become non-essential.
‘Analytical use — Extraction — Colour and food additive determination’	Use of ODS as an extraction solvent in the determination of colours and food additives. Nowadays these uses have usually become non-essential.
‘Analytical use — Extraction — Oil mist analysis’	Use of ODS as an extraction solvent in the determination of hydrocarbons in water and other media. This use is no longer considered as essential.
‘Analytical use — Extraction — Pesticide and heavy metal detection’	Use of ODS as an extraction solvent in the determination of pesticides and heavy metals. Nowadays these uses have usually become non-essential.
‘Analytical uses — Miscellaneous — Separation media’	Use of ODS as separation media, e.g. Soxhlet extractions, solid-phase extraction, etc. Nowadays these uses have usually become non-essential.
‘Analytical use — Reference — Chemical’	Use of ODS as a chemical reference material.
‘Analytical use — Reference — Product’	Use of ODS as a reference material for testing products (e.g. breathing filter tests, resistance testing).
‘Analytical use — Reference — Toxicant’	Use of ODS as a reference material in toxicological studies.
‘Analytical use — Tracer — Sanitary engineering’	Use of ODS as a tracer, e.g. to determine leakages in waste water pipes. This use is no longer considered as essential.
‘Analytical use — Samples containing ODS’	This refers to samples of ODS for laboratory and analytical investigations, e.g. quality control.
‘Laboratory use — Miscellaneous’	Use of ODS for the development or validation of new laboratory

Category	Explanation
(including biochemical) — Laboratory method development'	methods. While not prohibited, the use of ODS in new methods is not considered favourable. The use of ODS for validating old methods is usually not acceptable.
'Laboratory use — Miscellaneous (including biochemical) — Sample preparation using solvent'	Use of ODS as a diluent or solvent to prepare laboratory samples. Nowadays these uses have usually become non-essential.
'Laboratory use — Research and development — reaction solvent or feedstock'	Use of ODS in chemical synthesis in the context of research and development.
'Laboratory use — Sale to distributor'	This entry is to be used by distributors selling to other distributors or end users for several use categories.
'Laboratory use — other use (specified below)'	This refers to uses that do not fit into any of the categories above. There are hardly any of these uses left. Consult the Commission first before using this category.

7.2. Annex II: Non-exhaustive list of alternative methods

7.2.1. Determination of hydrocarbons (oil, grease, etc.) in water

Area	Old method using ODS	New method without ODS
Determination of polycyclic aromatic hydrocarbons by HPLC FID after liquid-liquid extraction		ISO 7981-1:2005
Determination of hydrocarbon oil index — using solvent (petroleum ether) extraction and gravimetry		ISO 9377-1:1998
Gas-chromatographic determination of monocyclic aromatic hydrocarbons, naphthalene and several chlorinated compounds after purge and trap		ISO 15680:2003
Determination of 15 polycyclic aromatic hydrocarbons (PAH) in water by HPLC after liquid-liquid extraction		ISO 17993:2002
Hydrocarbon oil index by gas chromatography after n-hexane extraction		ISO 93772:2000
Hydrocarbons in water	ASTM D3921-85 (1991)	ASTM D3921-96(2003)
Standard test method for dimer/trimer of chlorotrifluoroethylene (S-316) recoverable oil and grease and non-polar material by infrared determination	US EPA 418.1	ASTM D7066-04e1
Solvent-free membrane recoverable oil and grease by infrared determination		ASTM D7575-10e1
Volatile organic compounds in water by purge and trap capillary column gas chromatography with photoionization and electrolytic conductivity detectors in series		US EPA 502.2
Volatile organics by gas chromatography after purge and trap		US EPA 524.2
N-hexane extractable material and silica gel treated n-hexane extractable material by gravimetry	US EPA 413.1 US EPA 413.2	US EPA 1664 Revision A / EPA-821-R-98-002 May 1999
Separatory funnel liquid-liquid extraction		US EPA 3510C
Solid-phase extraction (SPE)		US EPA 3535
Soxhlet extraction		US EPA 3540c
Ultrasonic extraction		US EPA 3550b

Area	Old method using ODS	New method without ODS
Supercritical fluid extraction of total recoverable petroleum hydrocarbons by IR spectroscopy		US EPA 3560
Headspace gas chromatography		US EPA 3810
Hexadecane extraction and screening of purgeable organics		US EPA 3820
Non halogenated organics by GC/FID		US EPA 5015C
Aromatic and halogenated volatiles by gas chromatography using photoionization and/or electrolytic conductivity detectors		US EPA 5021B US EPA 8021B
Purge-and-trap for aqueous samples		US EPA 5030B
Non-halogenated organics by GC/FID		US EPA 8015C
Volatile organic compounds by gas chromatography/mass spectrometry		US EPA 8260B

7.2.2. *Determination of hydrocarbons (oil, grease, etc.) in soil or sediment*

Area	Old method using ODS	New method without ODS
Determination of organic and total carbon after dry combustion		ISO 10694:1995
Determination of polynuclear aromatic hydrocarbons by HPLC		ISO 13877:1988
Gas chromatographic determination of the content of volatile aromatic hydrocarbons, naphthalene and volatile halogenated hydrocarbons after methanol extraction and purge and trap		ISO 15009:2002
Determination of hydrocarbon content (C10 to C40) by gas chromatography after extraction with heptane)		ISO 16703:2004
Solvent extraction of total petroleum hydrocarbons from soil and sediments using closed vessel microwave heating		ASTM D5765-05
Supercritical fluid extraction of total recoverable petroleum hydrocarbons and IR spectroscopy		US EPA 3560
Volatile organic compounds by gas chromatography/mass spectrometry		US EPA 8260B

Area	Old method using ODS	New method without ODS
Aromatic and halogenated volatiles by gas chromatography using photoionization and/or electrolytic conductivity detectors		US EPA 5021B
n-Hexane extractable material for sludge, sediment, and solid samples (gravimetry)		US EPA 9071B

7.2.3. *Determination of hydrocarbons (oil, grease, etc.) in waste, air and other matrices*

Area	Old method using ODS	New method without ODS
Hydrocarbons (C10-C40) in waste by gas chromatography after heptane extraction		EN 14039:2004
Determination of hydrocarbon content in waste by gravimetry		EN 14345:2004
Volatile organic compounds by vacuum distillation in combination with gas chromatography/mass spectrometry (VD/GC/MS) (distillation and trapping)		US EPA 8261A
Air	US NIOSH 5026	US NIOSH TO 14 and 15
Tests for the assessment of surface cleanliness		ISO 8502 series

7.2.4. *Determination of iodine or bromine index*

Area	Old method using ODS	New method without ODS
Iodine value of animal and vegetable fats and oils	ASTM D1959-97 ASTM D 2710	ISO 3961:2009
Bromine index of aromatic hydrocarbons by coulometric titration	ASTM D2710-99	ASTM D1492-08e1
Bromine index of aromatic hydrocarbons by electrometric titration	ASTM D2710-99	ASTM D5776-07e1

7.2.5. Determination of moisture and water

Area	Old method using ODS	New method without ODS
Animal and vegetable fats and oils. Determination of moisture and volatile matter content (heating method)		ISO 662:1998
Animal and vegetable fats and oils. Determination of water content. Entrainment method		ISO 934:1980
Animal and vegetable fats and oils. Determination of water content. Karl Fischer method (pyridine free)		ISO 8534:2008
Petroleum products and bituminous materials. Determination of water. Distillation method		ISO 3733:1999
Petroleum products. Determination of water. Potentiometric Karl Fischer titration method		ISO 6296:2000
Petroleum products. Determination of water. Coulometric Karl Fischer titration method		ISO 12937:2000

7.2.6. Determination of phenol in water

Area	Old method using ODS	New method without ODS
Water quality — Determination of phenol index — 4-Aminoantipyrine spectrometric methods after distillation		ISO 6439:1990
Water quality — Determination of selected monovalent phenols — Part 1: Gas-chromatographic method after enrichment by extraction		ISO 8165-1:1992
Water quality — Determination of selected monovalent phenols — Part 2: Method by derivatization and gas chromatography		ISO 8165-2:1999
Water quality — Determination of phenol index by flow analysis (FIA and CFA)		ISO 14402:1999
Standard test methods for phenolic compounds in water (chloroform)		ASTM D1783-01:2007

7.2.7. *Miscellaneous methods*

Area	Old method using ODS	New method without ODS
Volatile matter in coal and coke	ASTM D3175-98	ASTM D3175-07
Testing of tar in road-paving materials		ASTM D2042-09 EN 12592:2007
Lead content in gasoline	ASTM D 3237:97	EN 237:2004 ASTM D 3237-06e1