

Notice to users of controlled substances in the European Union allowed for essential uses in the Community in 2009 under Regulation (EC) No 2037/2000 of the European Parliament and of the Council on substances that deplete the ozone layer

(2008/C 114/13)

I. This Notice concerns the following substances:

Group I: CFC 11, 12, 113, 114 or 115

Group II: other fully halogenated CFCs

Group III: halon 1211, 1301 or 2402

Group IV: carbon tetrachloride

Group V: 1,1,1-trichloroethane

Group VI: methyl bromide

Group VII: hydrobromofluorocarbons

Group VIII: hydrochlorofluorocarbons

Group IX: bromochloromethane

II. This notice is addressed to users that intend to:

1. use the above substances within the Community for the manufacture of Metered Dose Inhalers (MDIs);

2. acquire the above substances for laboratory and analytical uses directly from a producer or by import into the Community and not from any distributor of the substances inside the Community.

III. Controlled substances for essential uses may be obtained from production within the Community and, if necessary, by import from sources outside the Community.

IV. Decision IV/25 and Decision XIX/13 of the Parties to the Montreal Protocol on Substances that Deplete the Ozone Layer set out criteria and a procedure for determining 'essential uses' for which continued production and consumption are allowed after phase-out.

V. Article 3(1) of Regulation (EC) No 2037/2000 of the European Parliament and of the Council ⁽¹⁾ requires the determination of quantities for essential uses of the above-mentioned controlled substances which may be permitted in the Community in 2008 if no adequate alternatives are available and in accordance with Decision IV/25 and Decision XIX/13 of the Parties to the Montreal Protocol ⁽²⁾.

VI. The Parties to the Montreal Protocol may take a Decision in November 2008 authorising the maximum levels of production of CFCs for essential uses in 2009 for metered dose inhalers (MDIs) for the treatment of asthma and chronic obstructive pulmonary diseases as specified in Annex I, subject to the conditions established by the Meeting of the Parties in paragraph 2 of its Decision VII/28.

VII. Decision XVIII/15 and Decision XIX/18 of the Parties to the Montreal Protocol authorises the production and consumption necessary to satisfy essential uses of controlled substances listed in Annexes A, B and C (Group II and III substances) of the Montreal Protocol for laboratory and analytical uses. Authorised uses are listed in Annex IV to the report of the Seventh Meeting of the Parties, subject to the conditions set out in Annex II to the report of the Sixth Meeting of the Parties. The uses listed in paragraph 6 of Decision VII/11, subparagraphs (a) to (c) of Decision XI/15 and in subparagraph (3) of Decision XIX/18 are excluded from the allowed laboratory and analytical uses.

⁽¹⁾ OJ L 244, 29.9.2000, p. 1. Regulation as last amended by Commission Decision 2007/540/EC (OJ L 198, 31.7.2007, p. 35).

⁽²⁾ The list of active ingredients deemed essential for the production of CFC-MDI is available via: http://ozone.unep.org/Exemption_Information/Essential_Use_Nominations/Measures_by_Parties_to_facilitate_the_transition_to_chlorofluorocarbon_EC.shtml

- VIII. In accordance with Decision X/19 of the Parties to the Montreal Protocol, the purity of controlled substances for laboratory and analytical uses should be at least 99,0 % for 1,1,1-trichloroethane and 99,5 % for CFCs and carbon tetrachloride. These high purity substances and mixtures containing controlled substances shall be supplied only in re-closable containers or high pressure cylinders smaller than three litres or in 10 millilitre or smaller glass ampoules, marked clearly as substances that deplete the ozone layer, restricted to laboratory and analytical uses and specifying that used or surplus substances should be collected and recycled wherever possible. The material should be destroyed following the procedures described in Article 16(1) of the Regulation if recycling is not practical.
- IX. More information, including the texts of the relevant decisions of the Parties to the Montreal Protocol on laboratory and analytical uses quoted here above can be found at:

http://ec.europa.eu/environment/ozone/pdf/2006_lab.pdf

- X. The procedure for allocating quantities of controlled substances for the above essential uses carried out under Regulation (EC) No 2037/2000 and Regulation (EC) No 2038/2000 of the European Parliament and of the Council is the following:

1. An undertaking that has not been issued with a quota in 2008 and that requests consideration by the Commission for an essential use quota for the period 1 January 2009 to 31 December 2009 should make itself known to the Commission no later than **1 July 2008** by submitting the registration form for the Main-ODS-database available online at:

<http://ec.europa.eu/environment/ozone/ods.htm>

After their registration in the ODS-database it is necessary to follow the procedure described in 2.

2. Essential use applications may be made by any user of substances listed at the beginning of this Notice.

For CFCs for use in MDIs, all registered undertakings will receive an application form from the Commission.

For Laboratory Uses, each applicant should apply by completing the relevant Essential Laboratory Use form online via the ODS-database available at: <http://ec.europa.eu/environment/ozone/ods.htm>. In addition to the online submission a signed print of the import declaration form needs to be sent to the Commission:

European Commission
Directorate-General Environment
Unit ENV.C.4 — Industrial Emissions and Protection of the ozone layer
BU-5 2/053
B-1049 Brussels
Fax (32-2) 292 06 92
E-mail: env-ods@ec.europa.eu

A copy of the application should also be sent to the competent authority of the Member State. A list of contact points in all Member States is available online at:

http://ec.europa.eu/environment/ozone/ods_export.htm

- XI. Only applications received by **1 August 2008** will be considered by the Commission.
- XII. The Commission will issue quotas to those users and shall notify them of the use for which they have authorisation, the substance they are authorised to use and the quantity of the controlled substances concerned.
- XIII. Following the above procedure the Commission will notify applicants by a Decision of the quantities of controlled substances allowed for essential uses in the community in 2009 for which production and importation will be permitted.

- XIV. Those users holding an essential use quota for a controlled substance for 2009 will be able to make a request to a Community producer via the ODS-database or, if necessary, request an import licence from the Commission for a controlled substance up to their quota limit. The producer must be authorised by the competent authority of the Member State in which its relevant production is situated to produce the controlled substance for meeting that licensed demand. The competent authority of the Member State shall notify the Commission well in advance of any such authorisation.
-

ANNEX I

Substances covered

Group	Substances	Ozone-depleting potential (°)
Group I	CFCl ₃ (CFC 11)	1,0
	CF ₂ Cl ₂ (CFC 12)	1,0
	C ₂ F ₃ Cl ₃ (CFC 113)	0,8
	C ₂ F ₄ Cl ₂ (CFC 114)	1,0
	C ₂ F ₅ Cl (CFC 115)	0,6
Group II	CF ₃ Cl (CFC 13)	1,0
	C ₂ FCl ₃ (CFC 111)	1,0
	C ₂ F ₂ Cl ₄ (CFC 112)	1,0
	C ₃ FCl ₇ (CFC 211)	1,0
	C ₃ F ₂ Cl ₆ (CFC 212)	1,0
	C ₃ F ₃ Cl ₅ (CFC 213)	1,0
	C ₃ F ₄ Cl ₄ (CFC 214)	1,0
	C ₃ F ₅ Cl ₃ (CFC 215)	1,0
	C ₃ F ₆ Cl ₂ (CFC 216)	1,0
	C ₃ F ₇ Cl (CFC 217)	1,0
Group III	CF ₂ BrCl (halon 1211)	3,0
	CF ₃ Br (halon 1301)	10,0
	C ₂ F ₄ Br ₂ (halon 2402)	6,0
Group IV	CCl ₄ (carbon tetrachloride)	1,1
Group V	C ₂ H ₃ Cl ₃ (°) (1,1,1-trichloroethane)	0,1
Group VI	CH ₃ Br (methyl bromide)	0,6
Group VII	CHFBr ₂	1,00
	CHF ₂ Br	0,74
	CH ₂ FBr	0,73
	C ₂ HFBr ₄	0,8
	C ₂ HF ₂ Br ₃	1,8
	C ₂ HF ₃ Br ₂	1,6
	C ₂ HF ₄ Br	1,2
	C ₂ H ₂ FBr ₃	1,1
	C ₂ H ₂ F ₂ Br ₂	1,5
	C ₂ H ₂ F ₃ Br	1,6
	C ₂ H ₃ FBr ₂	1,7
	C ₂ H ₃ F ₂ Br	1,1
	C ₂ H ₄ FBr	0,1
	C ₃ HFBr ₆	1,5
	C ₃ HF ₂ Br ₅	1,9
	C ₃ HF ₃ Br ₄	1,8
	C ₃ HF ₄ Br ₃	2,2
	C ₃ HF ₅ Br ₂	2,0
	C ₃ HF ₆ Br	3,3
	C ₃ H ₂ FBr ₅	1,9
	C ₃ H ₂ F ₂ Br ₄	2,1

Group	Substances	Ozone-depleting potential (1)
	C ₃ H ₂ F ₃ Br ₃	5,6
	C ₃ H ₂ F ₄ Br ₂	7,5
	C ₃ H ₂ F ₃ Br	1,4
	C ₃ H ₃ FBr ₄	1,9
	C ₃ H ₃ F ₂ Br ₃	3,1
	C ₃ H ₃ F ₃ Br ₂	2,5
	C ₃ H ₃ F ₄ Br	4,4
	C ₃ H ₄ FBr ₃	0,3
	C ₃ H ₄ F ₂ Br ₂	1,0
	C ₃ H ₄ F ₃ Br	0,8
	C ₃ H ₅ FBr ₂	0,4
	C ₃ H ₅ F ₂ Br	0,8
	C ₃ H ₆ FBr	0,7
Group VIII	CHFC ₂ (HCFC 21) (3)	0,040
	CHF ₂ Cl (HCFC 22) (3)	0,055
	CH ₂ FCl (HCFC 31)	0,020
	C ₂ HFCl ₄ (HCFC 121)	0,040
	C ₂ HF ₂ Cl ₃ (HCFC 122)	0,080
	C ₂ HF ₃ Cl ₂ (HCFC 123) (3)	0,020
	C ₂ HF ₄ Cl (HCFC 124) (3)	0,022
	C ₂ H ₂ FCl ₃ (HCFC 131)	0,050
	C ₂ H ₂ F ₂ Cl ₂ (HCFC 132)	0,050
	C ₂ H ₂ F ₃ Cl (HCFC 133)	0,060
	C ₂ H ₃ FCl ₂ (HCFC 141)	0,070
	CH ₃ CFCl ₂ (HCFC 141b) (3)	0,110
	C ₂ H ₃ F ₂ Cl (HCFC 142)	0,070
	CH ₃ CF ₂ Cl (HCFC 142b) (3)	0,065
	C ₂ H ₄ FCl (HCFC 151)	0,005
	C ₃ HFCl ₆ (HCFC 221)	0,070
	C ₃ HF ₂ Cl ₅ (HCFC 222)	0,090
	C ₃ HF ₃ Cl ₄ (HCFC 223)	0,080
	C ₃ HF ₄ Cl ₃ (HCFC 224)	0,090
	C ₃ HF ₅ Cl ₂ (HCFC 225)	0,070
	CF ₃ CF ₂ CHCl ₂ (HCFC 225ca) (3)	0,025
	CF ₂ ClCF ₂ CHClF (HCFC 225cb) (3)	0,033
	C ₃ HF ₆ Cl (HCFC 226)	0,100
	C ₃ H ₂ FCl ₅ (HCFC 231)	0,090
	C ₃ H ₂ F ₂ Cl ₄ (HCFC 232)	0,100
	C ₃ H ₂ F ₃ Cl ₃ (HCFC 233)	0,230
	C ₃ H ₂ F ₄ Cl ₂ (HCFC 234)	0,280
	C ₃ H ₂ F ₅ Cl (HCFC 235)	0,520
	C ₃ H ₃ FCl ₄ (HCFC 241)	0,090
	C ₃ H ₃ F ₂ Cl ₃ (HCFC 242)	0,130
	C ₃ H ₃ F ₃ Cl ₂ (HCFC 243)	0,120
	C ₃ H ₃ F ₄ Cl (HCFC 244)	0,140
	C ₃ H ₄ FCl ₃ (HCFC 251)	0,010

Group	Substances	Ozone-depleting potential ⁽¹⁾
	C ₃ H ₄ F ₂ Cl ₂ (HCFC 252)	0,040
	C ₃ H ₄ F ₃ Cl (HCFC 253)	0,030
	C ₃ H ₃ FCl ₂ (HCFC 261)	0,020
	C ₃ H ₃ F ₂ Cl (HCFC 262)	0,020
	C ₃ H ₆ FCl (HCFC 271)	0,030
Group IX	CH ₂ BrCl Halon 1011/bromochloro-methane	0,120

⁽¹⁾ These ozone-depleting potentials are estimates based on existing knowledge and will be reviewed and revised periodically in the light of decisions taken by the Parties to the Montreal Protocol on Substances that Deplete the Ozone Layer.

⁽²⁾ This formula does not refer to 1,1,2-trichloroethane.

⁽³⁾ Identifies the most commercially-viable substance as prescribed in the Protocol.