COMMISSION

COMMISSION DECISION

of 20 December 1995

on the allocation of quantities of controlled substances allowed for essential uses in the Community in 1996 under Council Regulation (EC) No 3093/94 on substances that deplete the ozone layer

(95/555/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 3093/94 of 15 December 1994 [1], and in particular Articles 3, 4 and 7 thereof,

Whereas, because of concerns for the ozone layer, the Community has decided to phase out certain controlled substances earlier than provided for in the Montreal Protocol commencing on 1 January 1995;

Whereas Article 3 (1), (2), (3), (4), (5) and (7) of Regulation (EC) No 3093/94 states that the Commission shall determine every year any essential uses which may be permitted in the Community and any quantities of controlled substances which may be produced, placed on the market or used for these purposes;

Whereas, pursuant to the abovementioned Regulation, those essential uses have to be decided for chlorofluorocarbons (Articles 3 (1) and 4 (1)); other fully halogenated chlorofluorocarbons (Articles 3 (2) and 4 (2)); halons (Articles 3 (3) and 4 (3); carbon tetrachloride (Articles 3 (4) and 4 (4)); 1,1,1-trichloroethane (Articles 3 (5) and 4 (5)); and HBFCs (Articles 3 (7) and 4 (7));

Whereas the criteria used for assessing essential uses are in line with Decision IV/25 of the Parties to the Montreal Protocol and are:

(a) that a use of a controlled substance should qualify as 'essential' only if:

(i) it is a necessary for health or safety, or is critical for the functioning of society (including cultural and intellectual aspects); and

(ii) there are no technically and economically feasible alternatives or substitutes that are acceptable environmentally or from the health point of view;

(b) that production and consumption, if any, of a controlled substance for essential uses should be permitted only if:

(i) all economically feasible steps have been taken to minimize the essential use and associated emission of the controlled substance; and

(ii) the controlled substance is not available in sufficient quantity and quality from existing stocks of banked or recycled controlled substances, account also being taken of the needs of developing countries for controlled substances;

Whereas Decision VI/9 of the Parties to the Montreal Protocol authorizes the levels of production or consumption necessary to satisfy essential uses of controlled substances for (i) metered dose inhalers (MDIs) for the treatment of asthma and chronic obstructive pulmonary diseases (COPD) and for (ii) laboratory and analytical uses as specified in Annex I to this Decision;

Whereas the same Decision VI/9 also commits Parties to endeavouring to minimize use and emissions by all possible means; whereas in the case of MDIs, these means include educating physicians and patients about other treatment options and making real efforts to eliminate or recapture emissions from filling and testing consistent with national laws and regulations;

[1] OJ No L 333, 22. 12. 1994, p. 1.

Whereas after receiving a certain number of applications from Member States, the Commission published Decision 95/324/EC [1] which recognizes the production of MDIs for the treatment of asthma and other COPDs and laboratory uses as essential uses and specifies quantities for the European Community on behalf of the Member States for 1996, in line with the Montreal Protocol Decisions IV/25 and VI/9 mentioned above;

Whereas the quantity of 1,1,1-trichloroethane authorized in Decision 95/324/EC is not sufficient for the essential laboratory and analytical uses;

Whereas, in order to increase the quantities of 1,1,1-trichloroethane to meet the essential laboratory uses identified in Decision 95/324/EC, the Commission shall identify the distributors who may supply the controlled substances for that purpose;

Whereas the Commission has published a notice [2] to those companies in the European Community which use controlled substances that may be allowed for essential uses in the Community in 1996 pursuant to Regulation (EC) No 3093/94, and has thereby revealed applications for quantities of controlled substances for essential uses for 1996;

Whereas, in the framework of the Montreal Protocol nomination and assessment procedures for essential uses, parties are requested to identify the users who may take advantage of essential uses in 1996;

Whereas the Commission issues licences to the users identified pursuant to Articles 3, 4 and 7 and in accordance with the procedure set out in Article 16 of Regulation (EC) No 3093/94;

Whereas, consequently, within this framework a producer may be authorized by the competent authority of the Member State in which its relevant production is situated to produce the controlled substances for the purpose of meeting the licensed demands presented by the identified users; whereas the competent authority of the Member State concerned shall in turn notify the Commission well in advance of any such authorization;

Whereas Article 16 of Regulation (EC) No 3093/94 sets out the procedure according to which decisions can be taken concerning the implementation of the Regulation;

Whereas the measures provided for in this Decision are in accordance with the opinion of the Committee referred to in Article 16 of Regulation (EC) No 3093/94;

Whereas the list of essential uses and the quantities of the controlled substances are hereby given in Annex II as information for producer and user industries,

HAS ADOPTED THIS DECISION:

Article 1

Companies which may take advantage of essential uses for their own account or which put the controlled substances in free circulation with a view to exemptions being granted for essential laboratory uses are listed in Annex I.

Article 2

Further to Article 1 (1) of Decision 95/324/EC, the quantities of 1,1,1-trichloroethane for essential laboratory uses shall be increased by 300 tonnes.

Article 3

The allocation of quantities for essential uses is specified in Annex II.

Article 4

This Decision is addressed to the companies listed in Annex I.

Article 5

This Decision shall apply from 1 January to 31 December 1996.

Done at Brussels, 20 December 1995.

For the Commission

Ritt BJERREGAARD

Member of the Commission

[1] OJ No L 190, 11. 8. 1995, p. 13.
[2] OJ No C 221, 26. 8. 1995, p. 5.

ANEXO I — BILAG I — ANHANG I — ΠΑΡΑΡΤΗΜΑ I — ANNEX I — ANNEXE I — ALLEGATO I — BIJLAGE I — ANEXO I — LIITE I — BILAGA I

USOS MÉDICOS / MEDICINSKE ANVENDELSESFORMÅL / MEDIZINISCHE VERWENDUNGEN / ΙΑΤΡΙΚΕΣ ΧΡΗΣΕΙΣ / MEDICAL USES / UTILISATIONS MÉDICALES / USO MEDICO / MEDISCHE TOEPASSING / UTILIZAÇÕES MÉDICAS / LÄÄKETIETEELLINEN KÄYTTÖ / MEDICINSK ANVÄNDNING

3M Health Care Ltd
Mr A. J. Maynard
3M House
Morley Street
Loughborough
GB-Leicestershire LE11 1EP

Ankerpharm GmbH
Fr. Elzer-Vetter
Hansa-Allee 177 D
D-Düsseldorf

Laboratorio Astra España SA
Dr. E. Cabré Matas
Mestre Joan Corrales, 95-105
Esplugues de Llobregat
E-08950 Esplugues de Llobregat

Bespak PLC
Mr M. A. Talbot
Bergen Way
King's Lynn
GB-Norfolk PE30 2JJ

Boehringer Ingelheim GmbH
J. Pink
D-55216 Ingelheim/Rhein

CCL Industries Ltd
Mrs C. King
Astmoor Industrial Estate
9 Arkwright Road
GB-Runcorn WA7 1NU

Chiesi Farmaceutici SpA
Dr P. Chiesi
Via Palermo, 26/A
I-43100 Parma

Fisher Pharmaceuticals
Mr K. Gould
12 Derby Road
Loughborough
Leicesterhire
GB-LE11 0BB

Glaxo Manufacturing Services Ltd
Mr Jan Piskaldo
Priory Street
GB-Ware, Hertfordshire SG12 0DJ

IGS Sprühtechnik GmbH
F. Guck
Im Hemmet 1
D-79664 Wehr Baden

Jaba Farmacêutica
Ana Maria Baptista de Almeida
Apartado 165
Abrunheira
P-2710 Sintra

Leiras Oy
Pansiontie 47
PL 415
FIN-20101 Turku

Lesvi
Pol. Ind. Can Pelegrí
E-08740 Sant Andreu de la Barca (Barcelona)

Laboratorio Aldo-Unión SA
Dr. José Sabater Sanmartí
Àngel Guimerà, 123-125
E-08950 Esplugues de Llobregat

Norton Ltd
Mr Peter Earps
IDA Industrial Estate
Cork Road
IRL-Waterford

Orion-Farmos
Pasi Salokangas
Orionintie 1
PL 65
FIN-02101 Espoo

Pharmasol Ltd
Mr N. J. Ball
North Way
Walworth Industrial Estate, Andover
GB-Hampshire SP10 5AZ

Resolution Chemicals
Dr Chris Homan
Wodgewood Way
GB-Stevenage, Hertfordshire SG1 4QT

Rexam Dispenser SpA
Via del Pino, 10
I-22057 Olginate (Lecco)

Schering-Plough Labo N.V.
Ms Ingrid Van de Poel
Industriepark 30
B-2220 Heist op den berg

Sicor Società Italiana Corticosteroidi SpA
Dr Roberto Giani
Via Terrazzano, 77
I-20017 Rho (MI)

Valeas SpA Pharmaceuticals
Dr Virgilo Bernareggi
10, Via Vallisneri
I-20133 Milan

Société Valois
M. O. Fourment
50, avenue de l'Europe
F-78160 Marly-le-Roi

Vita
Mr Enric Vallès
Av. Barcelona, 69
E-08970 Sant Joan Despí

USOS DE LABORATORIO / LABORATORIEFORMÅL / VERWENDUNG ZU LABORZWECKEN / ΕΡΓΑΣΤΗΡΙΑΚΕΣ ΧΡΗΣΕΙΣ / LABORATORY USES / UTILISATIONS EN LABORATOIRE / USO PER SCOPI DI LABORATORIO / LABORATORIUMTOEPASSINGEN / UTILIZAÇÕES LABORATORIAIS / LABORATORIOKÄYTTÖ / LABORATORIE ANVÄNDNING

Ausimont SpA
Dr Enzo Giannetti
Viale Lombardia, 20
I-20021 Bollate

Bie & Berntsen AS
Mona Slothuus
Sandbækvej 7
DK-2610 Rødovre

Carlo Erba Reactifs
M. J.M. Ervay
Chaussée du Vexin
Parc d'Affaires des Portes
Boîte postale 616
F-27106 Val-de-Reuil

Carlo Erba Reagenti Srl
Dr Roberto Baschieri
Via Winckelmann, 1
I-Milano

Dehon Service
M. Claude Brian
26, avenue du Petit-Parc
F-94683 Vincennes Cedex

Dideco SpA
Mr Giorgio Sgarbi
Via Statale 12 Nord 86
I-41037 Mirandola

Laboratoires Domilens
M^me^ Christine Jacquemier
321, avenue Jean-Jaurès
Boîte postale 7254
F-69354 Lyon Cedex 07

Elf Atochem
(Centre de recherche Rhône-Alpes)
M. Paul Kiener
Rue Henri-Moissan
F-Pierre-Bénite Cedex

Elf Atochem
(Centre d'application de Levallois)
M. J.-P. Alais
95, rue Danton
Boîte postale 108
F-92303 Levallois-Perret

Fisia SpA
Strada Torino, 50
I-10043 Orbassano

Fisher Scientific Ltd
Mr G. Smith
Bishop Meadow Road
Loughborough
GB-Leicestershire LE11 0RG

Distillerie Haugel
M. Ferin
37, route de Saint-Laurent
Hameau de Gournay
F-76700 Gonfreville-l'Orcher

Ismar Chimica Srl
Dr Fabio de Paz
Via Isocorte, 16
I-16164 Genova

Lactan Ges.mbH & Co. KG
Walter Posch
Zinzendorfgasse 10-12
A-8011 Graz

Linna-Ryhmä Oy
Hannu Pesonen
Savilahdentie 6
FIN-70260 Kuopio

Mallinckrodt Baker B.V.
Mr Fleurink
Rijsterborgherweg 20
Postbus 1
NL-7400 AA Deventer

Merck Ltd
Mr P. E. Wall
Merck House
Poole
GB-Dorset BH15 1TD

Merck KGaA
K.-H. Mocikat
D-64271 Darmstadt

Mikrolab Aarhus
Axel Kiers 34
DK-8270 Højbjerg

OSI
M. J.-P. Frocot
Chemin de Montchevillon
F-02210 Oulchy-le-Château

Prolabo
M. H. Doucerain
54, rue Roger Salengro
F-94126 Fontenay-sous-Bois Cedex

Promochem GmbH
T. Karrer
Mercatorstr. 51
D-46485 Wesel

Renault VI
M^lle^ Claire Adenis
402, avenue Charles-de-Gaulle
F-69635 Vénissieux Cedex

Riedel-de-Haen
Dr. Creutzburg
Wunstorfer Str. 40
D-30926 Seelze

Romil Ltd
Dr R. Lenk
The Source
Convent Drive
Waterbeach
GB-Cambridgeshire CB5 9QT

SDS
M. Philippe Coste
ZI Valdonne
Boîte postale 4
F-13124 Peypin

Sigma-Aldrich Chimie s.a.r.l.
Me Karine Duval
L'Isle-d'Abeau-Chesnes
Boîte postale 701
F-38297 Saint-Quentin-Fallavier

Sigma-Aldrich Company Ltd
Dr Chris Hewitt
The Old Brickyard
New Road
Gillingham
GB-Dorset SP8 4JL

Sigma-Aldrich Chemie GmbH
Geschäftsbereich Aldrich
Dr. Gerd Backes
Riedstraße 2
D-89555 Steinheim

Sigma-Aldrich Chemie GmbH
Dr. Christoph Zimmermann
Geschäftsbereich Fluka
Messerschmittstr. 17
D-89231 Neu-Ulm

Vel N.V.
Dr Ronny Kennis
Geldenaaksebaan 464
B-3001 Leuven

Ya-Kemia Oy
Timo Posti
Kalliolanrinne 6
FIN-00510 Helsinki

ANNEX II

A. MEDICAL USES

Production of metered dose inhalers (MDIs) for the treatment of asthma and other chronic obstructive pulmonary diseases (CFCs)

(in tonnes)

Company	Quantity
3M (UK)	
Aldo Unión (E)	
Ankepharm (D)	
Astra (E)	
Bespak (UK)	
Boehringer (D)	
CCL Industries (UK)	
Chiesi Farmaceutici (I)	
Fisons Pharmaceuticals (UK)	
Glaxo (UK)	
IGS (D)	
Jaba (P)	
Leiras (FIN)	
Lesvi (E)	
Norton (IRL)	
Pharmasol (UK)	
Resolution Chemicals (UK)	
Rexam (I)	
Schering-Plough (B)	
Sicor (I)	
Valeas (I)	
Valois (F)	
Vita (E)	
Total	6 359,698

B. LABORATORY USES

B.1. CFCs

(in tonnes)

Company	Quantity
Ausimont (I)	
Bie & Berntsen (DK)	
Carlo Erba (F)	
Carlo Erba (I)	
Dehon (F)	
Dideco (I)	
Domilens (F)	
Elf Atochem (Centre de recherche Rhône-Alpes) (F)	
Fisia (I)	
Fisher (UK)	
Fluka (D)	
Lactan (A)	
Linna-Ryhmä (FIN)	
Mallinckrodt (NL)	
Merck (D)	
Merck (UK)	
Mikrolab (DK)	
Prolabo (F)	
Promochem (D)	
Riedel-de-Haen (D)	
Romil (UK)	
SDS (F)	
Sigma-Aldrich (D)	
Sigma-Aldrich (F)	
Sigma-Aldrich (UK)	
Vel (B)	
Ya-Kemia (FIN)	
Total	207,252

B.2. **Carbon tetrachloride**

(in tonnes)

Company	Quantity
Bie & Berntsen (DK)	
Carlo Erba (F)	
Carlo Erba (I)	
Fisia (I)	
Fluka (D)	
Ismar Chimica (I)	
Mallinckrodt (NL)	
Merck (D)	
Merck (UK)	
Mikrolab (DK)	
OSI (F)	
Prolabo (F)	
Promochem (D)	
Riedel-de-Haen (D)	
Romil (UK)	
SDS (F)	
Sigma-Aldrich (F)	
Sigma-Aldrich (UK)	
Sigma-Aldrich (D)	
Vel (B)	
Ya-Kemia (FIN)	
Total	233,95

B.3. 1,1,1-**Trichloroetane**

(in tonnes)

Company	Quantity
Elf Atochem (Centre de recherche Rhône-Alpes) (F)	
Elf Atochem (Centre d'application de Levallois) (F)	
Fisher (UK)	
Fluka (D)	
Haugel (F)	
Mallinckrodt (NL)	
Merck (D)	
Merck (UK)	
OSI (F)	
Prolabo (F)	
Renault (F)	
Romil (UK)	
Sigma-Aldrich (D)	
Sigma-Aldrich (F)	
Sigma-Aldrich (UK)	
Total	104,502