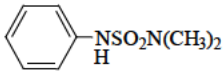


Section A2.8**Identity of impurities and additives (active Substance)**

Annex point IIA2.8

DIMETHYLAMINOSULFANILID (DMSA)

SubsectionOfficial
use only

2.8.1 Common name and function	Trivial name: Dimethylaminosulfanilid (DMSA), impurity
2.8.2 IUPAC name	N, N-Dimethyl- N'-phenylsulphamide
2.8.3 CAS-No	4710-17-2
2.8.4 EC-No	225-198-8
2.8.5 Other CIPAC	
2.8.6 Molecular formula	$C_8H_{12}N_2O_2S$
2.8.7 Structural formula	
2.8.8 Molecular mass	200.3 g/mol
2.8.9 Concentration of the impurity or additive typical and range of concentrations	<div style="background-color: black; width: 100%; height: 1em; margin-bottom: 5px;"></div> <div style="background-color: black; width: 100%; height: 1em;"></div>

Section A2.8**Identity of impurities and additives (active Substance)**

Annex point IIA2.8

BIS-DMSA SULFIDE

SubsectionOfficial
use only

2.8.1 Common name and function Trivial name: Bis-DMSA Sulfide,
Bis(dimethylamino sulfanilid sulfide)

impurity

2.8.2 IUPAC name N,N''-Thio-bis(N',N'-dimethyl - N-phenylsulfamide)

2.8.3 CAS-No 63538-66-9

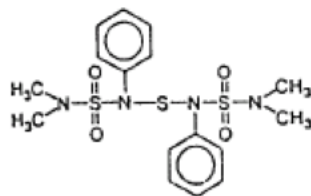
2.8.4 EC-No Not allocated

2.8.5 Other

CIPAC

2.8.6 Molecular formula C₁₆H₂₂N₄O₄S₃

2.8.7 Structural formula



2.8.8 Molecular mass 430.6 g/mol



2.8.9 Concentration of the impurity or additive
typical and range of concentrations

Section A2.8**Identity of impurities and additives (active Substance)**

Annex point IIA2.8

SODIUM CHLORIDE

SubsectionOfficial
use only

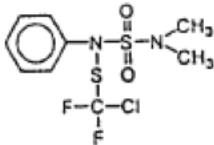
2.8.1 Common name and function	Sodium chloride, common salt impurity
2.8.2 IUPAC name	Sodium chloride
2.8.3 CAS-No	7647-14-5
2.8.4 EC-No	231-598-3
2.8.5 Other	
CIPAC	
2.8.6 Molecular formula	NaCl
2.8.7 Structural formula	Na ⁺ Cl ⁻
2.8.8 Molecular mass	58.4 g/mol
2.8.9 Concentration of the impurity or additive typical and range of concentrations	 

Section A2.8**Identity of impurities and additives (active Substance)**

Annex point IIA2.8

DIFLUOROEUUPAREN

SubsectionOfficial
use only

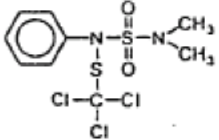
2.8.1 Common name and function	Trivial name: Difluoroeparen, impurity
2.8.2 IUPAC name	N-(Chlorodifluoromethylthio)-N',N'-dimethyl-N-phenylsulfamide, 1-Chloro-N-[(dimethylamino) sulfonyl]- 1,1-difluoro-N-phenyl- methanesulfenamide (CAS name)
2.8.3 CAS-No	Not allocated
2.8.4 EC-No	Not allocated
2.8.5 Other CIPAC	
2.8.6 Molecular formula	C ₉ H ₁₁ ClF ₂ N ₂ O ₂ S ₂
2.8.7 Structural formula	
2.8.8 Molecular mass	316.7 g/mol
2.8.9 Concentration of the impurity or additive typical and range of concentrations	<div style="background-color: black; width: 100px; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 200px; height: 15px;"></div>

Section A2.8**Identity of impurities and additives (active Substance)**

Annex point IIA2.8

TRICHLOROEUAREN

SubsectionOfficial
use only

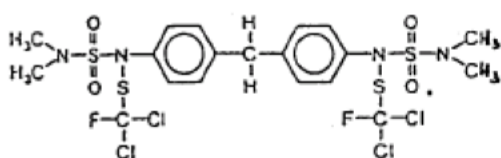
2.8.1 Common name and function	Trivial name: Trichloroeuparen, impurity
2.8.2 IUPAC name	N-(trichloromethylthio)-N',N'-dimethyl-N-phenylsulfamide, 1,1,1-Trichloro-N-(dimethylamino) sulfonyl-N-phenylmethanesulfenamide (CAS name)
2.8.3 CAS-No	Not allocated
2.8.4 EC-No	Not allocated
2.8.5 Other	
CIPAC	
2.8.6 Molecular formula	C ₉ H ₁₁ Cl ₃ N ₂ O ₂ S ₂
2.8.7 Structural formula	
2.8.8 Molecular mass	349.7 g/mol
2.8.9 Concentration of the impurity or additive typical and range of concentrations	████████████████████ ██

Section A2.8**Identity of impurities and additives (active Substance)**

Annex point IIA2.8

BIS-EUPAREN-METHYL

SubsectionOfficial
use only

2.8.1 Common name and function	Trivial name: Bis-Euparen-Methyl, impurity
2.8.2 IUPAC name	1,1-Bis[1,1-dichloro-N-[(methylamino) sulfonyl]-1-fluoro-N-[p-phenylmethanesulfenamide]methane
2.8.3 CAS-No	Not allocated
2.8.4 EC-No	Not allocated
2.8.5 Other	
CIPAC	
2.8.6 Molecular formula	$C_{19}H_{22}Cl_4F_2N_4O_4S_4$
2.8.7 Structural formula	
2.8.8 Molecular mass	678.5 g/mol
2.8.9 Concentration of the impurity or additive typical and range of concentrations	<div style="background-color: black; width: 100px; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 200px; height: 15px;"></div>

Section A2.8**Identity of impurities and additives (active Substance)**

Annex point IIA2.8

MAGNESIUM OXIDE

SubsectionOfficial
use only

2.8.1 Common name and function	Magnesia, Magnesium oxide additive (intentionally added for stabilisation of the technical active ingredient)
2.8.2 IUPAC name	Magnesium oxide
2.8.3 CAS-No	1309-48-4
2.8.4 EC-No	215-171-9
2.8.5 Other	
CIPAC	Not allocated
2.8.6 Molecular formula	MgO
2.8.7 Structural formula	Mg ²⁺ O ²⁻
2.8.8 Molecular mass	40.3 g/mol
2.8.9 Concentration of the impurity or additive typical and range of concentrations	██████████ ████████████████████ ██

Section A2.8**Identity of impurities and additives (active Substance)**

Annex point IIA2.8

SILICON DIOXIDE

SubsectionOfficial
use only

2.8.1 Common name and function	Silica, Silicon dioxide, [REDACTED]
2.8.2 IUPAC name	Silicon dioxide
2.8.3 CAS-No	7631-86-9
2.8.4 EC-No	231-545-4
2.8.5 Other	
CIPAC	
2.8.6 Molecular formula	SiO ₂
2.8.7 Structural formula	[SiO ₂] _n
2.8.8 Molecular mass	60.1 g/mol
2.8.9 Concentration of the impurity or additive typical and range of concentrations	[REDACTED] [REDACTED]

Section A2.8**Identity of impurities and additives (active Substance)**

Annex point IIA2.8

WHITE MINERAL OIL (PETROLEUM)

SubsectionOfficial
use only

2.8.1 Common name and function	White mineral oil, additive of [REDACTED]
2.8.2 IUPAC name	White mineral oil (petroleum) Saturated hydrocarbons having carbon numbers predominantly in the range of C15 through C50.
2.8.3 CAS-No	8042-47-5
2.8.4 EC-No	232-455-8
2.8.5 Other	
CIPAC	
2.8.6 Molecular formula	mixture
2.8.7 Structural formula	mixture
2.8.8 Molecular mass	mixture
2.8.9 Concentration of the impurity or additive typical and range of concentrations	[REDACTED] [REDACTED]

Section A2.8**Identity of impurities and additives (active Substance)**

Annex point IIA2.8

fill in one form for each impurity/additive

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
EVALUATION BY RAPporteur MEMBER STATE	
Date	08/02/2005
Materials and methods	Data provided from a five batch analysis (5BA) on impurities and additives of the technical active (Euparen) and the formulated active (Preventol A 4-S)
Conclusion	Applicant's version acceptable
Reliability	2
Acceptability	Acceptable
Remarks	UK CA agrees with data submitted for a 5BA on the impurities and additives of the technical active and the formulated active
COMMENTS FROM ...	
Date	<i>Give date of comments submitted</i>
Results and discussion	<i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	