

Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name): dapsone

Chemical Group:

EC Number: 201-248-4

CAS Number: 80-08-0

Submitted by: Germany

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Note

This document has been prepared by the evaluating Member State given in the CoRAP update.

Contents

1	IDENTITY OF THE SUBSTANCE.....	3
1.1	Other identifiers of the substance	3
2	CLASSIFICATION AND LABELLING.....	5
2.1	Harmonised Classification in Annex VI of the CLP	5
2.2	Self classification	5
2.3	Proposal for Harmonised Classification in Annex VI of the CLP	6
3	INFORMATION ON AGGREGATED TONNAGE AND USES.....	6
4	JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE.....	6
4.1	Legal basis for the proposal	6
4.2	Selection criteria met (why the substance qualifies for being in CoRAP)	6
4.3	Initial grounds for concern to be clarified under Substance Evaluation	7
4.4	Other completed/ongoing regulatory processes that may affect suitability for substance evaluation	7
4.5	Preliminary indication of information that may need to be requested to clarify the concern	8
4.6	Potential follow-up and link to risk management	8

1 IDENTITY OF THE SUBSTANCE

1.1 Other identifiers of the substance

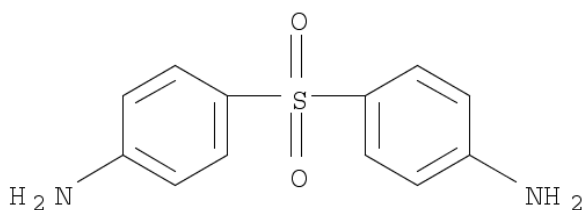
Table 1: Substance identity

EC name:	dapsone
IUPAC name:	4,4'-sulfonyldianiline
Index number in Annex VI of the CLP Regulation	612-084-00-1
Molecular formula:	C ₁₂ H ₁₂ N ₂ O ₂ S
Molecular weight or molecular weight range:	248.3 g/mol
Synonyms/Trade names:	<p>1,1'-Sulfonylbis<4-aminobenzene> 1358F 4,4'-Diaminodiphenyl sulfone 4,4'-Diaminodiphenyl sulphone 4,4'-Sulfonylbisaniline 4,4'-Sulfonylbisbenzamine 4,4'-Sulfonyldiphenylamine; 4-Aminophenyl sulfone Araldite HT 976 Aczone Aradur 9664-1 Aradur 976-1 Atrisone Avlosulfon Avlosulphone Bis(4-aminophenyl) sulfone Bis(p-aminophenyl) sulfone Croysulfone Croysulphone DADPS DDS DSS Di(4-aminophenyl)sulfone Di(p-aminophenyl) sulfone Diaphenylsulfon Diaphenylsulfone Diphenasone Diphone Disulone Dumitone Eporal F 1358 HB-MC-GE 40 HB-MC-GE 45 HT 9664 HT 976 HT 976-1</p>

	HY 976 Hardener HT 976 Lapox K 10 Metabolite C NSC 6091 Novophone Seikacure S Servidapson Sulfona Sulfona-Mae Sulphadione Somicure S Udolac p,p'-Diaminodiphenyl sulfone p,p'-Sulfonyldianiline p-Aminophenyl sulfone
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Type of substance Mono-constituent Multi-constituent UVCB

Structural formula:



1.2 Similar substances/grouping possibilities

None

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Classification		Labelling		Specific Concentration limits, M-Factors
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Supplementary Hazard Statement Code(s)	
Acute Tox. 4 *	H302	H302		

Signal Words:

Warning

Pictograms:

GHS07

2.2 Self classification

- In the registration

Classification		Labelling		Specific Concentration limits, M-Factors
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Supplementary Hazard Statement Code(s)	
Acute Tox. 3 *	H302	H302		

Signal Words:

Danger

Pictograms:

GHS07

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:

Classification		Labelling		Specific Concentration limits, M-Factors
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Supplementary Hazard Statement Code(s)	
STOT SE 1	H370	H370		
STOT RE 1	H372	H372		

Signal Words:

Danger

Pictograms:

GHS08

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

None

3 INFORMATION ON AGGREGATED TONNAGE AND USES

From ECHA dissemination site			
<input type="checkbox"/> 1 – 10 tpa	<input type="checkbox"/> 10 – 100 tpa	<input checked="" type="checkbox"/> 100 – 1000 tpa	
<input type="checkbox"/> 1000 – 10,000 tpa	<input type="checkbox"/> 10,000 – 100,000 tpa	<input type="checkbox"/> 100,000 – 1,000,000 tpa	
<input type="checkbox"/> 1,000,000 – 10,000,000 tpa	<input type="checkbox"/> 10,000,000 – 100,000,000 tpa	<input type="checkbox"/> > 100,000,000 tpa	
<input type="checkbox"/> <1 >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		<input checked="" type="checkbox"/> Confidential	
In addition there is a registration for intermediate use only, for which the tonnage is confidential.			
<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
Dapsone is mainly produced for industrial uses as adhesives and sealants and for polymer preparation and their compounds.			

4 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

4.1 Legal basis for the proposal

- Article 44(2) (refined prioritisation criteria for substance evaluation)
- Article 45(5) (Member State priority)

4.2 Selection criteria met (why the substance qualifies for being in CoRAP)

- Fulfils criteria as CMR/ Suspected CMR
- Fulfils criteria as Sensitiser/ Suspected sensitiser
- Fulfils criteria as potential endocrine disrupter
- Fulfils criteria as PBT/vPvB / Suspected PBT/vPvB
- Fulfils criteria high (aggregated) tonnage (*tpa* > 1000)
- Fulfils exposure criteria
- Fulfils MS's (national) priorities

4.3 Initial grounds for concern to be clarified under Substance Evaluation

Hazard based concerns		
CMR <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	Suspected CMR ¹ <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	<input checked="" type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser ¹	
<input type="checkbox"/> PBT/vPvB	<input type="checkbox"/> Suspected PBT/vPvB ¹	<input type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input type="checkbox"/> Exposure of environment	<input type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> High RCR	<input type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)
<p>There exists some evidence from in vitro studies and structure activity relation, which indicate the potential of an endocrine activity. Germany considers a substance evaluation necessary to check if the concerns regarding endocrine disrupting properties are sufficient to confirm that it is as endocrine disrupting substance for the environment.</p>		

4.4 Other completed/ongoing regulatory processes that may affect suitability for substance evaluation

<input type="checkbox"/> Compliance check, Final decision	<input type="checkbox"/> Dangerous substances Directive 67/548/EEC
<input type="checkbox"/> Testing proposal	<input type="checkbox"/> Existing Substances Regulation 793/93/EEC
<input checked="" type="checkbox"/> Annex VI (CLP)	<input type="checkbox"/> Plant Protection Products Regulation 91/414/EEC
<input type="checkbox"/> Annex XV (SVHC)	<input type="checkbox"/> Biocidal Products Directive 98/8/EEC ; Biocidal Product Regulation (Regulation (EU) 528/2012)
<input type="checkbox"/> Annex XIV (Authorisation)	<input type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> Annex XVII (Restriction)	
See section 2.1	

¹ CMR/Sensitiser: known carcinogenic and/or mutagenic and/or reprotoxic properties/known sensitising properties (according to CLP harmonized or registrant self-classification or CLP Inventory)

Suspected CMR/Suspected sensitiser: suspected carcinogenic and/or mutagenic and/or reprotoxic properties/suspected sensitising properties (not classified according to CLP harmonized or registrant self-classification)

Suspected PBT: Potentially Persistent, Bioaccumulative and Toxic

4.5 Preliminary indication of information that may need to be requested to clarify the concern

<input type="checkbox"/> Information on toxicological properties	<input type="checkbox"/> Information on physico-chemical properties
<input type="checkbox"/> Information on fate and behaviour	<input type="checkbox"/> Information on exposure
<input checked="" type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input checked="" type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)

Information on ED potential needed to clarify the concern may lead to the request of relevant fish toxicity studies including fish sexual development test or fish full life cycle. Further information on the ED potential as well as ecotoxicological data for invertebrate and vertebrates species is needed to clarify the concern.

4.6 Potential follow-up and link to risk management

<input type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input type="checkbox"/> Authorisation	<input checked="" type="checkbox"/> Other (provide further details)
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If concern is substantiated a SVHC-identification according to art. 57 f will be proposed.