

German Substance Database

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Implementation of 11238

German Regulatory Agencies

- Paul-Ehrlich-Institute (PEI)
- Federal Office of Consumer Protection and Food Safety (BVL)
- Federal institute for Medicinal Products and Medical devices (BfArM)
- German Institute of Medical Documentation and Information
- Surveillance by German states

Scopes in German Data Model

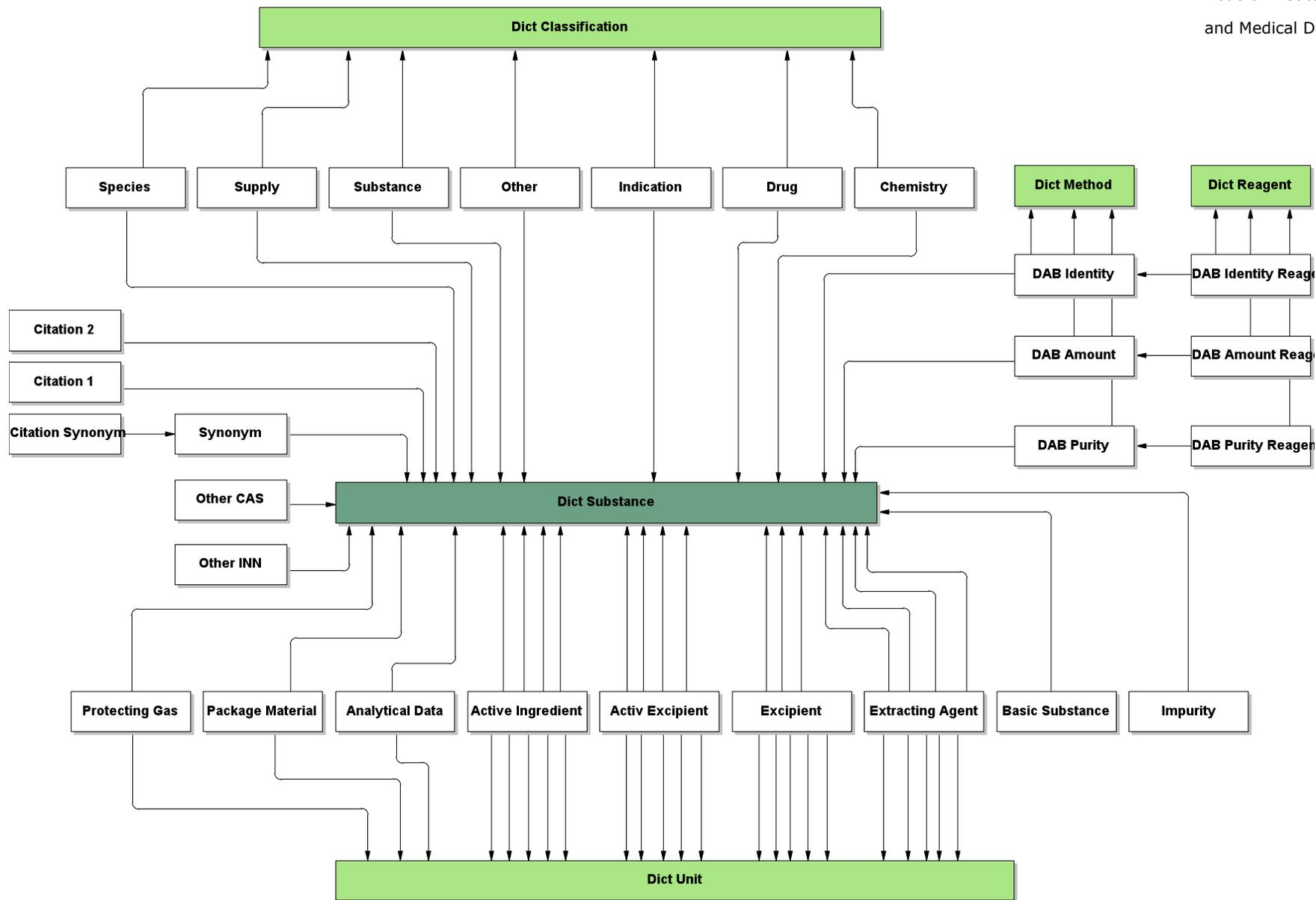
- Synonyms
- Identifier
- Physical and chemical properties
- Impurities
- Analytical information
- Classifications
- Phytopharmaka and Biologicals have to be improved

Contents of German Database

- Producer: BfArM, BVL, PEI
- Scope: substances related to business in the German NCAs
- Size: approx. 41.000 substances of all sorts of origins
 - » chemical, biological, herbal, blood, radiopharmaceuticals, homeopathic, anthroposophic ...
 - » active ingredients, excipients, gases, packaging materials, chemicals for analysis, impurities, substances prohibited by law etc.
- Names: 182.000 different names, synonyms, codes
- Content: ASK-Number
Molecular Formula, molecular weight,
synonyms
link to related substances
citations
different classifications and attributes
workflow information

Substance Name Ordinance

- Use of names for substances in medicinal products is regulated in Germany by legal ordinance
- Substance names according to law are published by DIMDI
- Source for publication is the internal database



Basic Information

Stoff-Nummer:	23761
ASK mit Prüfziffer:	23761-0
CAS-Nr.:	183814-30-4
Summenformel:	C ₄₂ H ₅₂ N ₄ O ₁₂ · 2 H ₂ O
Formelstamm:	2(C ₁₉ H ₂₄ N ₂ O ₄) · C ₄ H ₄ O ₄ · 2 H ₂ O
relative Molmasse:	840.9172
1. Bezeichnung:	Formoterolhemifumarat 1 H ₂ O
INN:	(INN.L21)
Andere INN:	(INNv.L44)
Zitat(e):	GII
2. Bezeichnung:	rac-N-(2-Hydroxy-5-{(1R)-1-hydroxy-2-{[(2R)-1-(4-methoxyphenyl)propan-2-yl]amino}ethyl}phenyl)formamid- [(2E)-but-2-endioat] (2:1) 2 H ₂ O
* 1.Synonym:	Formoterolfumarat (2:1) 2 H ₂ O
* 2.Synonym:	CGP 25827 A
Zitat(e):	(eINN.L21); (eINNv.L44)

Potential Impurities

1-(4-Methoxyphenyl)propan-2-amin

N-(2-Hydroxy-5-{1-[2-hydroxy-5-(1-hydroxy-2-[[1-(4-methoxyphenyl)propan-2-yl]amino}ethyl)anilino]-2-[[1-(4-methoxyphenyl)propan-2-yl]amino}ethyl}phenyl)formamid

rac-N-{2-Hydroxy-5-[(1R)-1-hydroxy-2-[[2S)-1-(4-methoxyphenyl)propan-2-yl]amino}ethyl]phenyl}formamid

rac-N-{5-[(1R)-2-{N-Benzyl-N-[(2S)-1-(4-methoxyphenyl)propan-2-yl]amino}-1-hydroxyethyl]-2-hydroxyphenyl}formamid

N-[2-Hydroxy-5-(1-hydroxy-2-[[1-(4-methoxy-3-methylphenyl)propan-2-yl]amino}ethyl)phenyl]formamid

N-[2-Hydroxy-5-(1-hydroxy-2-{N-[1-(4-methoxyphenyl)propan-2-yl]-N-methylamino}ethyl)phenyl]formamid

N-[2-Hydroxy-5-(1-hydroxy-2-[[1-(4-methoxyphenyl)propan-2-yl]amino}ethyl)phenyl]acetamid

Classification

Unspecific Classification

	Übereinkommen gegen Doping: 14. Änderung des Anhangs vom 21.06.2007 (01.01.2007) - Wirkstoffe und Methoden, die zu allen Zeiten verboten sind - Verbotene Wirkstoffe - S3. Beta-2-Agonisten
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Classification of Indication

	Antiasthmatikum
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	Bronchodilator
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	Beta-Sympathomimetikum
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Classification of Chemistry

	Carbonsäuren und Salze
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	Carbonsäureamide
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	Alkohole
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Current status

- No standard structure
- Structure not appropriate for biologicals
- Closed shop
- Classification of names not satisfying
- Need for more detailed information
- Some data only free text

Thank You!

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