

## Appendix 1: Acceptable intakes established for N-nitrosamines

Reference Number: EMA/307633/2024 /Rev. 5

### New chemical substances

Name	CAS RN	Source	CPCA Category	AI (ng/day)
<b>1-diphenylmethyl-4-nitrosopiperazine</b>	1698-25-5	Cinnarizine	3	400
<b>3-(dimethylamino)propyl 2-[benzyl(nitroso)amino]benzoate</b>	87453-76-7	Benzydamine	3	400
<b>N-Nitroso-bilastine impurity 2</b>	NA	Bilastine	3	400
<b>N-nitroso-caspofungin</b>	NA	Caspofungin	4	1500
<b>N-Nitroso-desformyl-riociguat</b>	NA	Riociguat	2	100
<b>N-nitroso-desmethyl-clarithromycin</b>	NA	Clarithromycin		NMI
<b>N-nitroso-desmethyl-tramadol</b>	NA	Tramadol	1	18
<b>N-nitroso-desvaleryl-valsartan</b>	2254485-68-0	Valsartan		NMI
<b>N-nitroso-N-desmethyl-diphenhydramine</b>	55855-43-1	Dimenhydrinate/ Diphenhydramine	1	18
<b>N-nitroso-tigecycline</b>		Tigecycline		NMI
<b>N-nitroso-trandolapril</b>	NA	Trandolapril	5	1500

### Updates of limits for some already listed nitrosamines

Name	CAS RN	Source	CPCA Category	AI (ng/day)
<b>Nitroso-STG-19</b>	2892260-32-9	Sitagliptin	No value => 2	37 => 100
<b>N-nitroso-desmethyl-citalopram</b>	NA	Citalopram	1 => No value	18 => 100
<b>N-nitroso-diisopropylamine</b>	601-77-4		No value => 5	26.5 => 1500
<b>N-nitroso-ethylisopropylamine</b>	16339-04-1		No value => 3	26.5 => 400
<b>N-nitroso-N-methyl-4-aminobutyric acid</b>	61445-55-4		No value => 4	96 => 1500

### Correction of typographical errors

Name	CAS RN	Source	CPCA Category	AI (ng/day)
<b>1-(2,3-dichlorophenyl)-4-nitrosopiperazine</b>	2221987-86-4	Ecuzumab => Aripiprazole	3	400
<b>N-nitroso-N-desmethyl-dextromethorphan</b>	NA	Dextromethorphan	5 => 4	1500