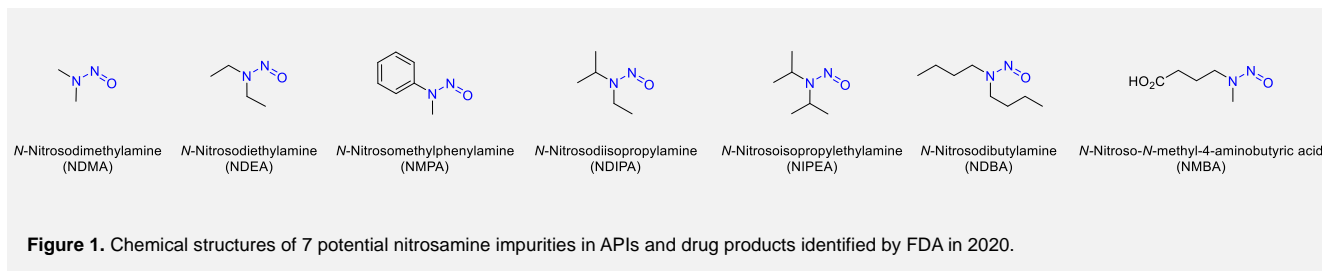


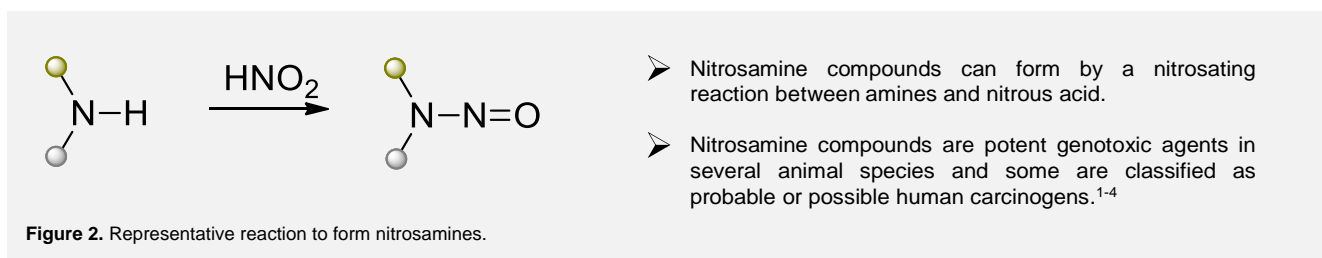
# N-Nitrosamines

## Introduction

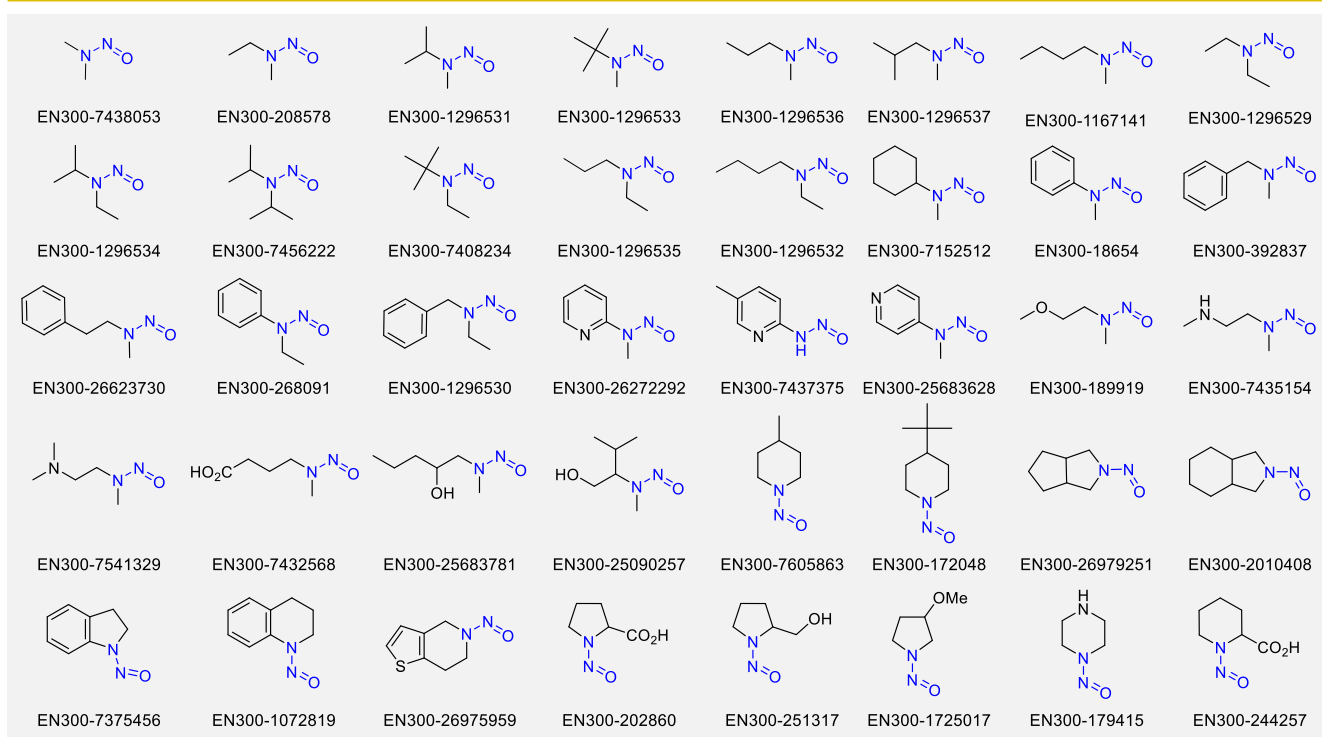
In 2018, nitrosamine impurities became a focus for authorities, when a recall of angiotensin II receptor blocker (ARB) medicines, known as “sartans”, was announced. In bioactive compounds, a toxic impurity, *N*-nitrosodimethylamine (NDMA), was found. Since then, more cases of drug product batches contaminated with nitrosamines came to be known (Ranitidine, Nizatidine and Metformin). In 2020, FDA announced the availability of a guidance for industry, entitled “Control of *N*-Nitrosamine Impurities in Human Drugs.”<sup>1</sup> In this context, Enamine offers a library of various nitrosamines for investigation.



## Case studies



We offer: more than 50 of nitrosamines from stock on a 5-10 g scale.



## References

- <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/control-nitrosamine-impurities-human-drugs>.
- <https://ntp.niehs.nih.gov/ntp/roc/content/profiles/nitrosamines.pdf>
- N.T. Crosby et al. *Adv. Food Res.* **1976**, *22*, 1.
- I. W. Ashworth et al. *Org. Process Res. Dev.* **2020**, *24*, 1629.



ご興味があるものがあれば、こちらまでお問い合わせ下さい!!



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