11 Stability and Storage Conditions

Methylpyrrolidone is stable at temperatures up to 800°C in the absence of air.[3] Store protected from light and moisture.[3]

12 Incompatibilities

Methylpyrrolidone is unreactive except in the presence of strong acids or bases. It may form complexes with metals, metal alkali salts, and some active pharmaceutical ingredients, including benzocaine, phenol, and iodine.[3] It is noncorrosive and biodegradable.[3]

13 Method of Manufacture

Methylpyrrolidone is produced by the condensation of butyrolactone with methylamine.[3]

14 Safety

Methylpyrrolidone is considered a poison when injected via the intravenous route. It is moderately toxic by ingestion, skin contact, and intraperitoneal routes. It is an experimental teratogen; mutagenicity data have been reported.[5]

LD_{50} (mouse, IP): 3.05 g/kg[5]
LD_{50} (mouse, IV): 0.0545 g/kg
LD_{50} (mouse, oral): 5.13 g/kg
LD_{50} (rabbit, SC): 8.0 g/kg
LD_{50} (rat, IP): 2.472 g/kg
LD_{50} (rat, IV): 0.0805 g/kg
LD_{50} (rat, oral): 3.914 g/kg

M

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. When heated to decomposition, methylpyrrolidone emits toxic fumes of nitrogen oxides (NO_x).

In the UK, the workplace exposure limits for methylpyrrolidone are 40 mg/m^3 (10 ppm) long-term (8-hour TWA) and 80 mg/m^3 (20 ppm) short-term (15 minutes).[6]

16 Regulatory Status

Included in the FDA Inactive Ingredients Database (periodontal drug delivery system; subcutaneous injection).

17 Related Substances

Pyrrolidone.

18 Comments

The FDA Inactive Ingredients Database gives a maximum potency of 25.85% for methylpyrrolidone when used in subcutaneous injections. A specification for methylpyrrolidone is included in the *Japanese Pharmaceutical Excipients* (JPE).[7]

The EINECS number for methylpyrrolidone is 212-828-1. The PubChem compound ID for methylpyrrolidone is 8454.

19 Specific References

1 Babu RJ, Pandit JK. Effect of penetration enhancers on the transdermal delivery of bupranolol through rat skin. *Drug Deliv* 2005; 12(3): 165–169.
2 Cilurzo F, *et al.* An insight into the skin penetration enhancement mechanism of *N*-methylpyrrolidone. *Mol Pharm* 2014; 11(3): 1014–1021.
3 GAF Corporation Chemical Division. *M-Pyrol*, *N*-Methyl-2-Pyrrolidone Handbook, 1st edn. New York: GAF Corporation Chemical Division, 1972.
4 Ashland Inc. Product data sheet: *M-Pyrol*, 2014.
5 Lewis RJ, ed. *Sax's Dangerous Properties of Industrial Materials*, 12th edn. New York: Wiley, 2012: 3106–3107.
6 Health and Safety Executive. *EH40/2005: Workplace Exposure Limits*. Sudbury: HSE Books, 2011. http://www.hse.gov.uk/pubns/priced/eh40.pdf (accessed 5 February 2016).
7 Japan Pharmaceutical Excipients Council. *Japanese Pharmaceutical Excipients 2004*. Tokyo: Yakuji Nippo, 2004: 547–548.

20 General References

Reochem Inc. Product data sheet: *n*-Methyl Pyrrolidone. http://www.reochem.com.au/files/downloads/Industrial_n-Methyl_Pyrrolidone_PDS_Apr10.pdf (accessed 5 February 2016).

21 Author

B Hancock.

22 Date of Revision

4 May 2017.

Mineral Oil

1 Nonproprietary Names

BP: Liquid Paraffin
JP: Liquid Paraffin
PhEur: Paraffin, Liquid
USP-NF: Mineral Oil

2 Synonyms

Avatech; *Drakeol*; heavy liquid petrolatum; heavy mineral oil; liquid petrolatum; paraffin oil; paraffinum liquidum; *Sirius*; white mineral oil.

3 Chemical Name and CAS Registry Number

Mineral oil [8012-95-1] and [8042-47-5]

4 Empirical Formula and Molecular Weight

Mineral oil is a mixture of refined liquid saturated aliphatic (C_{14}–C_{18}) and cyclic hydrocarbons obtained from petroleum. The USP 39–NF 34 specifies that mineral oil may contain a suitable stabilizer.

5 Structural Formula

See Section 4.